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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

 Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

130

Complete if Known	
Application Number	10/747,974
Filing Date	December 30, 2003
First Named Inventor	George M Levinson
Examiner Name	(TBA)
Art Unit	(TBA)
Attorney Docket No.	06335.00007

METHOD OF PAYMENT (check all that apply)				FEE CALCULATION (continued)																																																																																																																																																																																																																											
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ADDITIONAL FEES <table border="1"> <thead> <tr> <th>Large Entity</th> <th>Small Entity</th> <th colspan="2"></th> </tr> <tr> <th>Fee Code</th> <th>Fee (\$)</th> <th>Fee Code</th> <th>Fee (\$)</th> </tr> </thead> <tbody> <tr> <td>1051</td> <td>130</td> <td>2051</td> <td>65</td> <td colspan="2">Surcharge - late filing fee or oath</td> </tr> <tr> <td>1052</td> <td>50</td> <td>2052</td> <td>25</td> <td colspan="2">Surcharge - late provisional filing fee or cover sheet.</td> </tr> <tr> <td>1053</td> <td>130</td> <td>1053</td> <td>130</td> <td colspan="2">Non-English specification</td> </tr> <tr> <td>1812</td> <td>2,520</td> <td>1812</td> <td>2,520</td> <td colspan="2">For filing a request for reexamination</td> </tr> <tr> <td>1804</td> <td>920*</td> <td>1804</td> <td>920*</td> <td colspan="2">Requesting publication of SIR prior to Examiner action</td> </tr> <tr> <td>1805</td> <td>1,840*</td> <td>1805</td> <td>1,840*</td> <td colspan="2">Requesting publication of SIR after Examiner action</td> </tr> <tr> <td>1251</td> <td>110</td> <td>2251</td> <td>55</td> <td colspan="2">Extension for reply within first month</td> </tr> <tr> <td>1252</td> <td>420</td> <td>2252</td> <td>210</td> <td colspan="2">Extension for reply within second month</td> </tr> <tr> <td>1253</td> <td>950</td> <td>2253</td> <td>475</td> <td colspan="2">Extension for reply within third month</td> </tr> <tr> <td>1254</td> <td>1,480</td> <td>2254</td> <td>740</td> <td colspan="2">Extension for reply within fourth month</td> </tr> <tr> <td>1255</td> <td>2,010</td> <td>2255</td> <td>1,005</td> <td colspan="2">Extension for reply within fifth month</td> </tr> <tr> <td>1401</td> <td>330</td> <td>2401</td> <td>165</td> <td colspan="2">Notice of Appeal</td> </tr> <tr> <td>1402</td> <td>330</td> <td>2402</td> <td>165</td> <td colspan="2">Filing a brief in support of an appeal</td> </tr> <tr> <td>1403</td> <td>290</td> <td>2403</td> <td>145</td> <td colspan="2">Request for oral hearing</td> </tr> <tr> <td>1451</td> <td>1,510</td> <td>1451</td> <td>1,510</td> <td colspan="2">Petition to institute a public use proceeding</td> </tr> <tr> <td>1452</td> <td>110</td> <td>2452</td> <td>55</td> <td colspan="2">Petition to revive - unavoidable</td> </tr> <tr> <td>1453</td> <td>1,330</td> <td>2453</td> <td>665</td> <td colspan="2">Petition to revive - unintentional</td> </tr> <tr> <td>1501</td> <td>1,330</td> <td>2501</td> <td>665</td> <td colspan="2">Utility issue fee (or reissue)</td> </tr> <tr> <td>1502</td> <td>480</td> <td>2502</td> <td>240</td> <td colspan="2">Design issue fee</td> </tr> <tr> <td>1503</td> <td>640</td> <td>2503</td> <td>320</td> <td colspan="2">Plant issue fee</td> </tr> <tr> <td>1460</td> <td>130</td> <td>1460</td> <td>130</td> <td colspan="2">Petitions to the Commissioner</td> </tr> <tr> <td>1807</td> <td>50</td> <td>1807</td> <td>50</td> <td colspan="2">Processing fee under 37 CFR 1.17 (q)</td> </tr> <tr> <td>1806</td> <td>180</td> <td>1806</td> <td>180</td> <td colspan="2">Submission of Information Disclosure Stmt</td> </tr> <tr> <td>8021</td> <td>40</td> <td>8021</td> <td>40</td> <td colspan="2">Recording each patent assignment per property (times number of properties)</td> </tr> <tr> <td>1809</td> <td>770</td> <td>2809</td> <td>385</td> <td colspan="2">Filing a submission after final rejection (37 CFR § 1.129(a))</td> </tr> <tr> <td>1810</td> <td>770</td> <td>2810</td> <td>385</td> <td colspan="2">For each additional invention to be examined (37 CFR § 1.129(b))</td> </tr> <tr> <td>1801</td> <td>770</td> <td>2801</td> <td>385</td> <td colspan="2">Request for Continued Examination (RCE)</td> </tr> <tr> <td>1802</td> <td>900</td> <td>1802</td> <td>900</td> <td colspan="2">Request for expedited examination of a design application</td> </tr> <tr> <td colspan="4">Other fee (specify) <input type="text"/></td> <td colspan="4"></td> </tr> <tr> <td colspan="4">*Reduced by Basic Filing Fee Paid</td> <td colspan="4">SUBTOTAL (3) (\$ 130)</td> </tr> <tr> <td colspan="8"> SUBTOTAL (1) (\$ 0) </td> </tr> <tr> <td colspan="8"> SUBTOTAL (2) (\$ 0) </td> </tr> <tr> <td colspan="8"> *For number previously paid, if greater; 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SUBMITTED BY						Complete (if applicable)	
Name (Print/Type)	Robert H. Resis	Registration No. (Attorney/Agent)	32,168	Telephone	(312) 463-5000		
Signature				Date	January 28, 2004		

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Express Mail No. EV306398878US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No. 06335.00007)



In the Application of:)
George M. Levinson et al.)
Serial No.: 10/747,974) Group Art Unit: (TBA)
Filed: December 30, 2003) Examiner: (TBA)
For: System, Method, and Computer-Readable)
Medium for Collection of Environmental)
Data and Generation of User Report for)
Compliance with FDA Requirements)

PETITION TO MAKE SPECIAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

Applicants respectfully petition to make the above-cited application special for accelerated examination pursuant to 37 CFR 1.102 and MPEP 708.02 (VIII). The above-cited application has not received any examination by the examiner. The Patent Office is authorized to charge the required fee for this petition to make special as set forth in 37 CFR 1.17(h) to Account No. 19-0733.

All of the claims are directed to a single invention, or if the Office determines that all of the claims presented are not obviously directed to a single invention, the Applicants will make an election without traverse as a prerequisite to the grant of special status. A pre-examination search was made

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by a prior art search firm, listing the field of search by class and subclass, publication, Chemical Abstracts, foreign patents, etc. The field of Search included:

FIELD OF SEARCH

<u>CLASS</u>	<u>SUBCLASS</u>
422	62
700	90, 108, 109, 111, 266, 276, 277, 299, 300

Attached is a copy of each reference found in the search (Reference Nos. 1-15), and a copy of U.S. Patent No. 5,838,906, cited in the application (Reference No. 16), and a copy Reference Nos. 17-21, which refer to the Environmental Monitoring Software System (EMSS), owned by the assignee of the application, and which is cited in the application. The following is a detailed discussion of the references, which identifies with the particularity required by 37 CFR 1.111 (b) and (c), how the claimed subject matter is patentable over the references.

1. U.S. Patent No.4,298,955 discloses a system for detecting and analyzing deviations from normal in the operating conditions of a process, for example a chemical manufacturing process. The system comprises transducers positioned to detect a plurality of operating parameters and generate signals representative of the said parameters. A processing device is connected to receive the signals and programmed to analyze the signals on the basis of a decision table having columns each of which represents a different combination of operating parameter values. Each column has associated therewith a value representing the seriousness of the deviation represented by the

combination of values. Means are provided for displaying, storing and/or recording the nature of each deviation analyzed by the processing device and the value associated therewith. Systems for transmitting data from transducers to a receiver and for analyzing data are also provided.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

2. U.S. Patent No. 5,103,391 discloses a highly distributed direct digital process control system for use in controlling a fully distributed process includes at least one device controller independently monitoring and controlling a plurality of external devices for performing a complete process. One or more data concentrator units are connected to the controllers for collecting information from each controller as well as directing updated control information to specific controllers. A central information processing means is connected to the data concentrator for displaying information received from the data concentrator. The central information processing means is capable of updating control information used by specific controllers.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected

from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

3. U.S. Patent No. 5,691,895 discloses a comprehensive, generic mechanism models, monitors, controls and optimizes manufacturing as an on-line, real-time system employing statistical analysis and mathematical techniques with feedback and forward information for local control and global optimization. Manufacturing is treated as a hierarchy of processes which are modeled, controlled, optimized and managed via four interacting networks; an application modeling network, a local control network, a global optimization network, and an implementation/management network. Of these four networks, only the application modeling network is application dependent. The functions of the other three networks are application independent. All manufacturing processes, from simple process steps through manufacturing sectors and lines, to complete factories, are treated identically, thereby simplifying computational complexity. A minimal set of parameters is thereby obtained at any manufacturing level, which reduces a complex manufacturing process to a manageable form. Outputs of lower level processes in the hierarchy become input process variables for higher levels. Process models are developed and updated via on-line data analysis, and are used to evaluate process status and improvement path.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler,

facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

4. U.S. Patent No. 5,719,796 discloses a statistical simulation of a semiconductor fabrication process is performed in parallel with the actual process. Input parameters derived from a probability density function are applied to the simulator which, in turn, simulates an actual fabrication process which is modeled as a probability density function. Each simulation step is repeated with a random seed value using a Monte Carlo technique, a trial-and-error method using repeated calculations to determine a best solution to a problem. The simulator generates an output in the form of a probability distribution. The statistical simulation uses single-step feedback in which a simulation run uses input parameters that are supplied or derived from actual in-line measured data. Output data generated by the simulator, both intermediate output structure data and WET data, are matched to actual in-line measured data in circumstances for which measured data is available. The probability density structure of the simulator is adjusted after each simulation step so that simulated data more closely matches in-line measured data.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

5. U.S. Patent No. 5,787,021 discloses an information system for production control wherein measured data from many test facilities is controlled, stored, and, if necessary, processed in a central data base. Via two-way data links, various data users can access the stored data and use this data for their own purposes. Thus it is possible, for example, to retrieve production figures of individual products or entire product ranges, complied statistics, calculate costs, determine yields, and the like. Access by the individual data users to the data base takes place via a terminal or a personal computer, with which nearly every work place is equipped and which are electronically interconnected via a data network for the exchange of data.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

6. U.S. Patent No. 5,798,945 discloses small modules directly situated at power outlets in buildings, that contain at least one sensor gather and report local environmental data such as temperature, humidity, carbon dioxide concentration, motion, particulate matter concentration, carbon monoxide, methane, or other parameters. The local modules report data back over existing building power wiring to a central unit. The central unit may store or reduce data for reporting over to a computer over a conventional RS-232 link. The data can be used to prove compliance with

environmental and safety regulations and requirements or used to control HVAC equipment. Also, the data can be displayed or used with energy price tier systems.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

7. U.S. Patent No. 5,862,054 discloses a method to monitor process parameters from multiple process machines to provide real time statistical process control (SPC). The particular implementation was derived from ion implantation of wafers, but has wide applicability where there are a number of process machines having a number of process parameters and close continuous sampling of data is required. The process parameters are collected on a single computer over a single RS 485 network, and each parameter is analyzed and displayed separately for each process and process machine. Statistical variables like Cp and Cpk are calculated and presented on the computer screen along with graphs of the various parameters for a particular process machine. Data is aged out of the computer to an archival data base under the control of a manufacturing information system and connected to a company wide network.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the

environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

8. U.S. Patent No. 5,892,690 discloses an environment monitoring system and method for systematically and continuously monitoring an environment. The system and method includes a data acquisition system which is programmed to systematically collect environment data for a site. The data acquisition system includes sensors coupled to a data storage device having a remote access device for electronic access from a remote system. Data may be uploaded to a remote database for storing environment data from many sites. The remote database includes a remote access device so that the data storage devices of various data acquisition sites can be electronically coupled to the remote database for centralized data collection and storage.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

9. U.S. Patent No. 6,163,732 discloses systems, methods and computer program products to determine compliance of a chemical product to be manufactured to government

regulations that govern the manufactured product. According to the invention, the chemical compositions that are present in the chemical product to be manufactured are ascertained. The chemical compositions so ascertained are compared to a stored set of government regulatory standards related to the chemical compositions to determine compliance. Accordingly, compliance with complex government regulations governing chemical products can be determined.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

10. U.S. Patent No. 6,523,045 discloses a method for managing information about a manufacturing operation uses factory screens, shop floor screens and/or the like of a shop floor control graphical user interface. The factory screen graphically represents a factory. The shop floor screens represent different shop floors or other areas of the factory. These areas of the factory are represented by selectable icons, positioned within the factory screen at locations corresponding to the locations of the represented areas within the factory. Each shop floor screen depicts the general appearance of one of the areas of the factory and the factory elements of that area of the factory. Icons representing factory elements are positioned within the shop floor screens at locations corresponding to the locations of the represented factory elements within the corresponding shop

floor. Icons representing machines and storage locations include graphics depicting the appearance of the represented machine or storage location.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

11. U.S. Patent No. 6,539,271 discloses a quality management system and computer based process for managing quality. The quality management system includes a set of networked operator stations for entering data including critical to quality customer information and information relating to the equipment to be monitored on a quality basis. The system further includes an application server on the network for running the programs of the system such as critical to quality setup, report generation, logging to the database, and maintenance events. A database server is further included on the network for storing the local database. A web server holding a capability warehouse connects to the local database over a web connection. The process for managing the quality of the monitored electrical equipment includes sending process capability data from the local database to the capability warehouse, updating an entitlement database embedded in the capability warehouse, delivering new schema information to the local database from the entitlement database, and reporting information to the customer at an operator station via an automatic or requested report.

This reference does not teach the present invention, for example a data management system

having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

12. U.S. Patent No. 5,631,839 discloses a device for controlling a complex manufacturing process. The device comprises at least one remote monitor designed to receive in real time signals through a local area network making it possible to analyze the state of the manufacturing process. There are a plurality of sensors, each of the sensors transforming the value of an associated parameter of the manufacturing process so as to produce an analogue signal. There is an analogue to digital converter associated with each of the sensors for producing a succession of numerical values representing the instantaneous state over time of the corresponding parameter. Each of the converters is interfaced with the local area network. A processor for processing the numerical values and comparing them with given reference values is also connected to the local area network such that the local area network conveys the result of the comparison to the remote monitor or monitors and also conveys the information coming from the analogue to digital converter to the processing means.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler,

facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

13. U.S. Patent No. 6,437,692 discloses a system for monitoring a variety of environmental and/or other conditions within a defined remotely located region. In accordance with one aspect of the invention, a system is configured to monitor utility meters in a defined area. The system is implemented by using a plurality of wireless transmitters, wherein each wireless transmitter is integrated into a sensor adapted to monitor a particular data input. The system also includes a plurality of transceivers that are dispersed throughout the region at defined locations. The system uses a local gateway to translate and transfer information from the transmitters to a dedicated computer on a network. The dedicated computer, collects, compiles, and stores the data for retrieval upon client demand across the network. The computer further includes means for evaluating the received information and identifying an appropriate control signal, the system further including means for applying the control signal at a designated actuator.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

14. U.S. Patent No. 6,574,522 discloses a system and method for handling quality control data for a manufacturing process among a main computer and a plurality of remote computers, including the steps of establishing a connection between at least one of the remote computers and the main computer via a web browser, inputting quality control data of the manufacturing process from the remote computer into a database of the main computer via the web browser, performing a statistical analysis on the quality control data input into the main computer, and posting results of the statistical analysis on a web site of the main computer accessible to the remote computers through the web browser.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

15. U.S. Patent No. 6,604,023 discloses environmental indicators computed for a particular environment and converted into a transmittable data format. Each of the environmental indicators is computed by electronic environmental measurement device from among multiple diverse electronic environmental measurement devices. Environmental indicators are transmitted to a portable data processing system associated with a user, which analyzes each of the environmental indicators according to an environment sensitivity profile stored at the portable data processing system for the user. Control signals are determined by the portable computer system for adjusting

multiple environment control systems that control the particular environment in response to the analysis, such that a particular environment is temporarily managed by a portable data processing system according to environmental sensitivities of a particular user located within that particular environment.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

16. U.S. Patent No. 5,838,906 discloses a system allowing a user of a browser program on a computer connected to an open distributed hypermedia system to access and execute an embedded program object. The program object is embedded into a hypermedia document much like data objects. The user may select the program object from the screen. Once selected the program object executes on the user's (client) computer or may execute on a remote server or additional remote computers in a distributed processing arrangement. After launching the program object, the user is able to interact with the object as the invention provides for ongoing interprocess communication between the application object (program) and the browser program. One application of the embedded program object allows a user to view large and complex multi-dimensional objects from within the browser's window. The user can manipulate a control panel to change the viewpoint used to view the image. The invention allows a program to execute on a remote server or other computers to calculate

the viewing transformations and send frame data to the client computer thus providing the user of the client computer with interactive features and allowing the user to have access to greater computing power than may be available at the user's client computer.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

17. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets), located at <http://www.csoftsol.com/emss.html>. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

manufacturers, who must comply with strict quality control requirements of governmental bodies.

This system meets the requirements of 21 CFR Part 11.

This reference does not teach the present invention, for example a data management system having a universal hub in electronic communication with at least one piece of equipment used to automatically measure environmental data, the system configured to collect and store the environmental data, and generate a user report of the environmental data, the equipment selected from the group consisting of a particle counter, organism identification system, viable air sampler, facility monitoring system, rapid organism enumeration technology device, bioluminescence device, and water quality detector, the user report providing document compliance with U.S. Food and Drug Administration requirements.

18. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (2 sheets), located at http://www.bd.com/contentmanager/b_article.asp?ContentID=2655&d=&s=. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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19. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (3 sheets), located at <http://www.bd.com/industrial/Catapult/BDCatapultv4n1.pdf>. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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20. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS), in connection with 21 CFR Part 11 Compliance Assessment (4 sheets), located at www.csoftsol.com/21CFRPart11FinalStatement.pdf. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device

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21. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (168 sheets), located at www.csoftsol.com/CSSCPresBinder.pdf. The Environmental Monitoring Software System (by Compliance Software Solutions Corp. of Vernon Hills, Illinois, the assignee of the present invention), provides a cost effective and efficient means to manually enter into a computer database program the presence of viable microbiological organisms, the presence of particulates and other environmental conditions within the facility, such as humidity, pressure, temperature, water quality (e.g., pH, conductivity, total organic content (TOC), endotoxin, coliform, and metals), and the respective amounts of different materials involved in the manufacture of the end product(s). Thus, this system provides a means to access and document facility operations and store and trend data to ensure that the environmental control systems of a facility are operating as intended. This system is particularly useful for pharmaceutical, biotechnology, and medical device manufacturers, who must

comply with strict quality control requirements of governmental bodies. This system meets the requirements of 21 CFR Part 11.

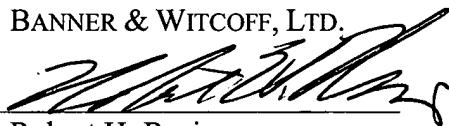
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In view of the foregoing, the Applicants respectfully request that the Petition to Make Special be granted and that the application be advanced for examination.

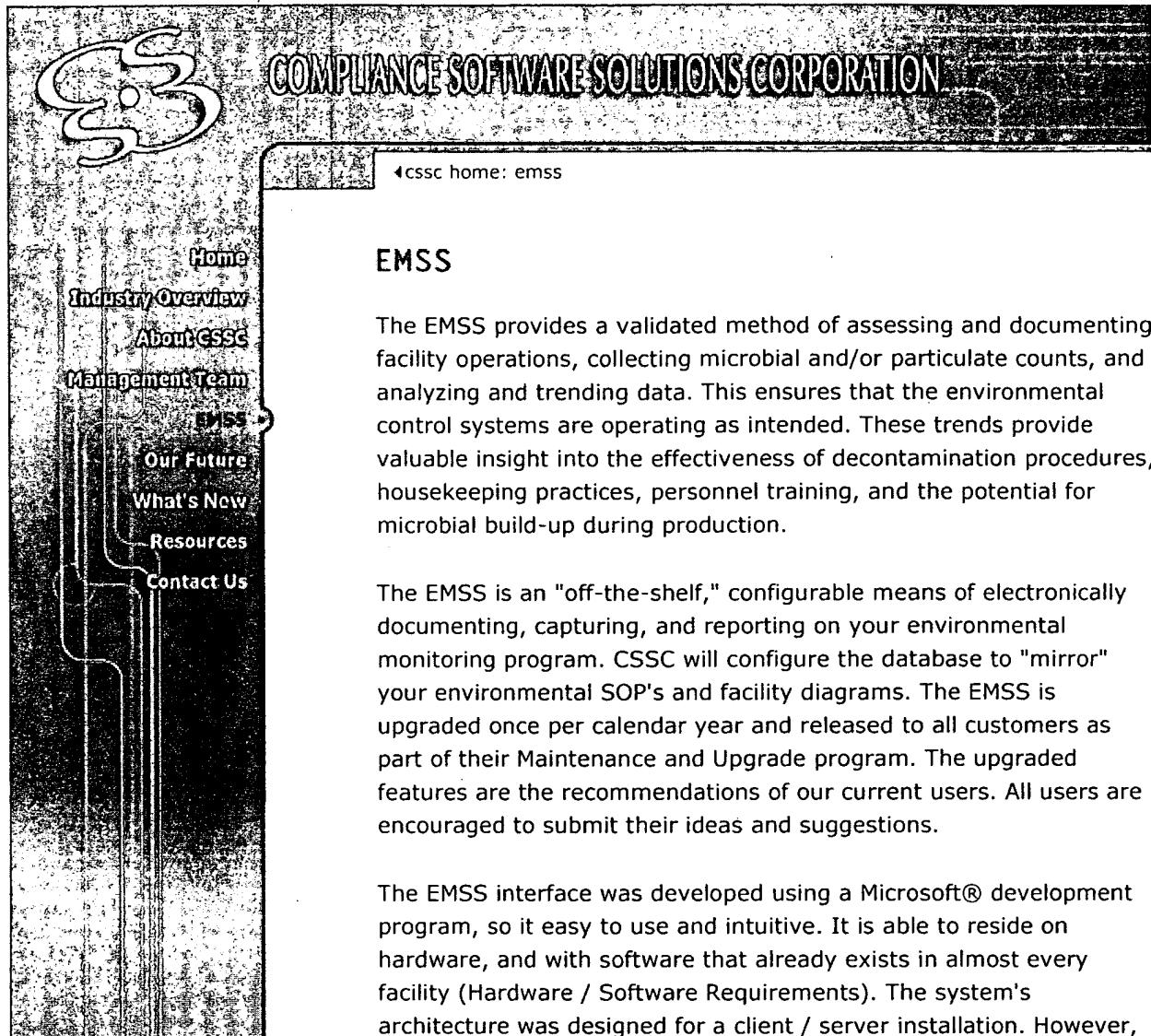
Respectfully submitted,

BANNER & WITCOFF, LTD.

Dated: January 28, 2004

By: 

Robert H. Resis
Reg. No. 32,168
Direct Dial: (312) 463-5405



EMSS

The EMSS provides a validated method of assessing and documenting facility operations, collecting microbial and/or particulate counts, and analyzing and trending data. This ensures that the environmental control systems are operating as intended. These trends provide valuable insight into the effectiveness of decontamination procedures, housekeeping practices, personnel training, and the potential for microbial build-up during production.

The EMSS is an "off-the-shelf," configurable means of electronically documenting, capturing, and reporting on your environmental monitoring program. CSSC will configure the database to "mirror" your environmental SOP's and facility diagrams. The EMSS is upgraded once per calendar year and released to all customers as part of their Maintenance and Upgrade program. The upgraded features are the recommendations of our current users. All users are encouraged to submit their ideas and suggestions.

The EMSS interface was developed using a Microsoft® development program, so it easy to use and intuitive. It is able to reside on hardware, and with software that already exists in almost every facility (Hardware / Software Requirements). The system's architecture was designed for a client / server installation. However, several of our customers have successfully implemented the EMSS on a Citrix® or Terminal Server®. It can be installed in virtually any network environment, is compatible with all operating systems, and is available to run with either an Oracle® or SQL Server® database.

Included with your site license for the EMSS is:

- A copy of the EMSS Software Validation Package
- System Use SOP
- Template document for performing the Installation Qualification (IQ)
- Template document for performing the Operational Qualification (OQ)
- Template document for performing the Performance Qualification (PQ)
- User Manuals

- Training Manuals

Some of the key functionality of the EMSS includes:

- On demand reporting that enables the user to review trends by site location and date range
- Supports a wide variety of predefined tests (i.e. particulate, microbial) as well as user defined tests (i.e. pH and chemical), including water testing
- Generates Worksheets (data sheets) and corresponding Barcode Labels to facilitate sample identification
- Custom visual layouts of facilities and test sites utilizing Microsoft Visio®
- Embedded digital photographs and video capabilities
- Automatic e-mail notification with attached historical data trend for "Alert Level" conditions
- Automatic e-mail notification with historical data trend and corrective action report generation for "Action Level" excursions
- Automatic e-mail notification with accompanying review of historical data in the event that a "flagged" organism is identified
- On-line review confirmation
- Tracks media expiration
- Tracks equipment calibration dates

Features that address the requirements of 21 CFR Part 11 includes:

- Multiple levels of security that restrict access and data modifications
- Electronic signature feature required for any additions, modifications, deletions, or reviews performed throughout the system
- Security lock-out feature
- Security time-out feature
- Password expiration
- A secure, non-modifiable, read-only / print-only audit trail automatically captures all modifications within the database

Click on the following [link](#) to download a PDF copy of CSSC's 21 CFR Part 11 Assessment Statement of the EMSS.

Click on the following [link](#) to download a PDF Presentation Binder. It includes a number of screen shots and reports from the EMSS.

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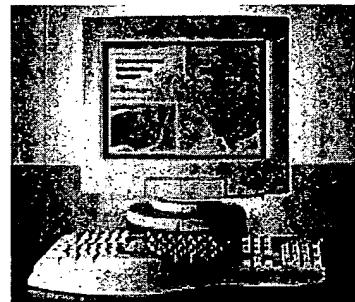
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Innovative Environmental Monitoring Software

Automates Data Management, Enables Regulatory Compliance

BD Diagnostic Systems, Sparks, MD, announces that it has recently launched a program built around its partnership with Compliance Software Solutions Corporation (CSSC), the developer of a unique software that automates data management for environmental monitoring. The partnership enables BD customers to enjoy the unprecedented advantages of CSSC's Environmental Monitoring Software System, known simply as EMSS. To be useful for tracking environmental contamination, data should be trended, reviewed, reported and assessed quickly. EMSS can collect, document and trend environmental monitoring data for audits and inspections, and can likewise provide critical information on the quality of the aseptic processing environment during manufacturing. This is especially beneficial for industries charged with meeting ever more stringent and changing regulatory requirements. EMSS can greatly impact businesses where environmental monitoring data is often only tracked manually via logbooks and spreadsheets – making data difficult to manage and use effectively. Compared with the management and utilization difficulties of manually tracking data in logbooks or spreadsheets, EMSS vastly improves the ability of businesses to efficiently comply with those stringent regulatory requirements.

EMSS offers BD customers a means to achieve compliance with industry regulations such as those outlined by the FDA, CFR, ISO and cGMP. EMSS automatically generates e-mails when alert or action conditions are met, or when organisms are flagged for follow-up. Use of the software can prevent the release of potentially contaminated batches if appropriate standards are not followed. Future contamination can be prevented as well because adverse trends can be detected and addressed much more quickly.

In an era when increased regulatory attention has been focused on environmental monitoring, BD is providing a meaningful, manageable and

defendable system that utilizes industry guidelines. The EMSS software package is a unique "off-the-shelf" solution to the management of environmental data, yet it can be configured to each client's facility. It can manage a full range of environmental testing at client facilities for both viable and non-viable contamination. EMSS can also support a wide range of predefined tests (e.g. particulates and microbial), all methods of water testing and can manage any user-defined tests such as pH and chemistry.

EMSS will be distributed exclusively by BD. It completes the BD breadth-of-line for environmental monitoring applications— working as an adjunct to BD BBL™ Sterile Pack Prepared Plated Media, BD Sterile Pack Swabs, BD Sterile Pack Bottles and air monitoring systems that utilize BD media. Future value-added software modules are planned for EMSS, specifically a fully automated interface with the BD Phoenix™ Microbiology System. For more information about EMSS, please call 1-800-638-8663, or contact your BD Diagnostic Systems representative.

CSSC and EMSS are trademarks of Compliance Software Solutions Corporation. BD, BBL and Phoenix are trademarks of Becton, Dickinson and Company. ©2003 BD January 2003

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BD Catapult

Propelling applications development in the areas of Biopharm Production, QA/QC & Environmental Monitoring

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Implementation of an Automated System for Environmental Monitoring

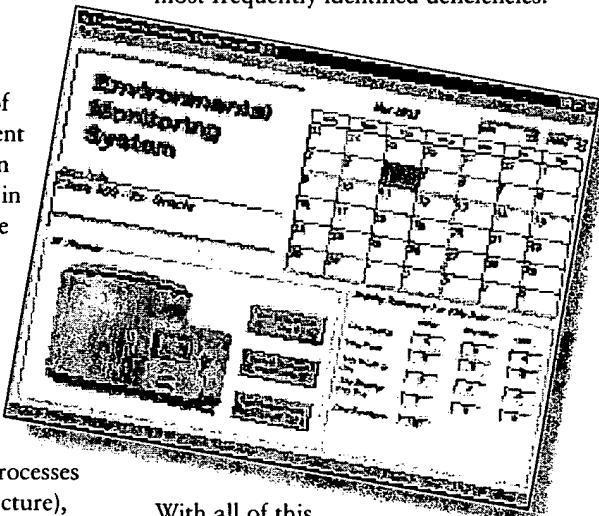
*Jeanne E. Moldenhauer
Vectech Pharmaceutical Consultants, Inc.*

Background-Regulatory Expectations

In September 2002, the Food and Drug Administration (FDA) released a Concept Paper, "Sterile Drug Products Produced By Aseptic Processing Draft." This paper provides an indication of FDA's thinking on aseptic processing and provided an opportunity for industry comment prior to issuance of the revised guidance document on aseptic processing. Within this paper, FDA states that "in aseptic processing, one of the most important laboratory controls is the establishment of an environmental monitoring program."

Environmental monitoring is also applicable to other types of processing (e.g., terminal sterilization processes and non-sterile drug manufacture), with aseptic processing being the most stringent application of these monitoring programs. The intent of these programs is to identify potential routes of product contamination and take appropriate corrective actions prior to contamination occurring. The paper also discusses many expectations for an environmental monitoring program.

In addition to the release of the "Concept Paper," there has been an increased interest in environmental monitoring by regulators worldwide. Numerous adverse findings reports have been issued in recent years, with environmental monitoring one of the most frequently identified deficiencies.



With all of this regulatory focus on environmental monitoring, it is important to have a meaningful, manageable and defendable program that will withstand the rigors of inspection by regulatory bodies. A significant problem with the design of this type of system is that a large volume of data is generated. The data is only useful if it can be trended,



Implementation of an Automated System for Environmental Monitoring

Continued from page 1

reviewed, reported and assessed in a timely manner. Finding out during a regulatory inspection that the environmental monitoring data exhibits a trend is not useful. It is important to know that a trend is occurring when it happens. Manual systems for data tracking and trending have inherent time delays in assessing the data. The time delay increases with the quantity of data generated. The "Concept Paper" defines specific expectations for trending of data (e.g., "data generated by location, lot, room, operator, or other search parameters") and specialized reports, like tracking the locations of an atypical isolate throughout the facility. Figure 1 provides some examples of the trending reports available from the Environmental Monitoring Software System (EMSS).

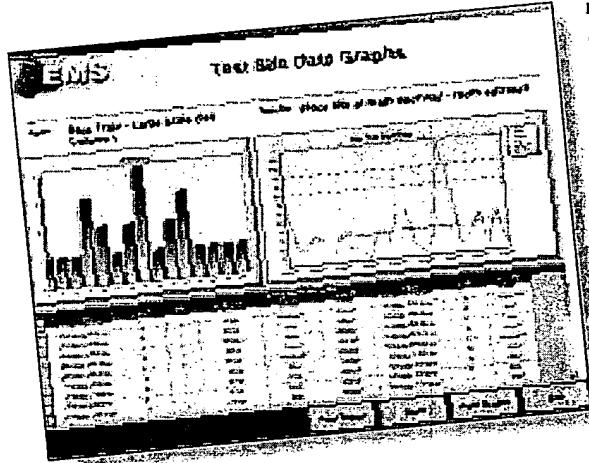


Figure 1 - Example of EMSS Trending Report

of Compliance Software Solutions Corporation. The reports generated by this system have been designed to meet the regulatory requirements for environmental monitoring. These expectations almost necessitate implementation and use of an automated system.

In considering automation of an environmental monitoring system, it is important to assess whether the existing monitoring system (manual) is working effectively, what requirements

must be met for the automated system, which part(s) of the system will be automated and how will automation affect the other parts of the system. A common problem in automating a system is the failure to look at the entire system when addressing what should be automated. For example, will data be both collected and reported automatically? Another problem is that you cannot effectively automate a bad system. If it doesn't work already, automating it only makes it worse than it was before.

Typical Approach to Automation
In considering a switch to an automated system for environmental monitoring, the following describes a typical approach for selection and implementation of a new system:

Evaluate/assess the existing system

- Look for compliance to applicable requirements and for the effectiveness of the system to provide a meaningful, manageable and defendable system.
- Review the documentation requirements in PDA Technical Report No. 13 (Revised) on Environmental Monitoring to ensure that all required documentation is collected. Figure 2 provides an example of a data entry screen from the EMSS system. This system has been designed to

ensure that all required documentation is maintained and generated.

- Verify the effectiveness of cleaning/disinfection systems and the accuracy of data management systems, that alert and action levels are established and appropriate, and that reports are appropriate and accurate.
- Evaluate how discrepancies and corrective actions are handled and resolved.

Evaluate opportunities for automation

- Some typical considerations here include: 21 CFR Part 11 compliance issues, opportunities to go paperless, integration of testing equipment with the automated system, etc.
- Part of this evaluation includes assessing what are the risks/costs associated with manual support operations. Automated systems come in a wide variety of applications; e.g., spreadsheets, LIMS systems, custom designed software and off-the-shelf software. There are risks and benefits associated with each type of system.

Evaluate vendors

After selecting the level of automation required and the type of system desired, one selects an appropriate vendor to support the system. Considerations for selecting vendors include:

- Technical knowledge of vendor relative to environmental monitoring
- Financial stability of vendor
- Ability of vendor to meet FDA requirements and support FDA review of the system
- Technical support available for the system
- Validation support available for the system. Software audits are often conducted to evaluate the vendor's capabilities at their site. There are very few suppliers of off-the-shelf software for environmental monitoring, including EMSS.

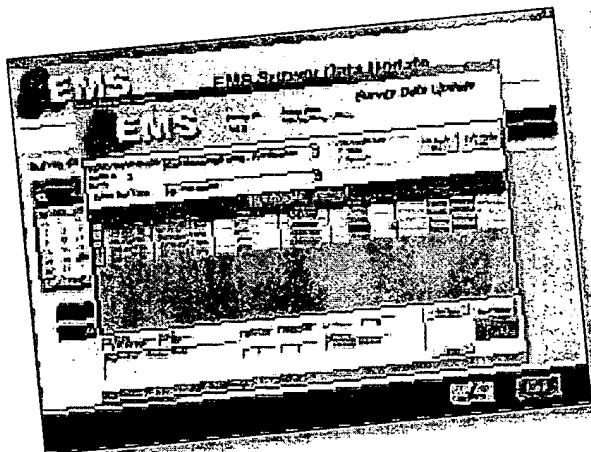


Figure 2 - Sample of EMSS Data Entry Screen

Select software

Defining and specifying software system requirements is a key ingredient to the selection of an appropriate system.

- When preparing these requirements, it is important that a team reviews and approves the specifications, to ensure that important characteristics are not inadvertently omitted.
- It is also important to identify which specifications are mandatory versus those that are optional. For example, when purchasing an off-the-shelf software package, one may need to accept a slightly different report format than has been used in the past. These specifications are also useful when developing the system validation requirements.
- It is important to consider the type of documentation that will support the system when specifying requirements; e.g., is a user's manual required, are sample validation protocols included, etc. Figure 3 includes a partial listing of the types of documentation provided with the EMSS system.

Figure 3
List of EMSS Documentation

User Manual
License Agreements
System Use SOP
Training Manuals
Validation Package
Validation Templates
(IQ, OQ, and PQ)

Install the software

- The computers and networks to be used with the selected system should be validated prior to installation of the software. Some companies choose to install concurrently, but this should be controlled. For example, lack of network validation for a networked monitoring system can lead to aberrations or problems at a later time.
- The system should be subjected to commissioning, debugging and "engineering" type studies to ensure that problems are minimized prior to initiating formal validation studies.

- One may also include some basic training for operators at this time.
- Many software systems also require establishment of facility drawings, parameter tables, etc., prior to validation testing.

Validate the software

Development of validation requirements should be well thought out.

- Vendors may provide validation protocols, but it is the end-user's responsibility to determine whether any other features or system integrations should be added to the testing protocol.
- One should also consider how the system will be re-qualified.
- It can be useful to establish standard data files that allow for easy repetition of data entry or reporting to minimize subsequent validation requirements; e.g., what testing will be required to replace computer boards, operating systems, etc.
- Typically, an Installation Qualification, Operational Qualification and Performance Qualification are performed. Figure 4 includes an index of a typical validation protocol for EMSS.

Implement the system

Following the validation, the system is implemented for production use.

On-going Evaluation and Maintenance

- The system should be evaluated periodically to ensure that it is still operating as designed and expected.
- Maintenance activities should also be performed and documented.

Obsolescence

At some point in time, all systems are obsoleted. Plans should be established for how these activities will be controlled and documented.

EMSS has been designed to meet the requirements for environmental monitoring systems. Figures from EMSS have been provided courtesy of Compliance Software Solutions Corporation. Additional screen shots from the EMSS system are included, to provide guidance on how this type of system can be controlled and documented.

BD Diagnostic Systems is an exclusive distributor for EMSS in North America. For further information regarding EMSS, contact your local BD Sales Representative or fill out and return the request for information card included with this newsletter.

Figure 4 Index of CSSC Validation Package for EMSS

Validation Report
Validation Protocol
Validation Management Plan
Requirements
Design
Process Flow Diagrams
Program Interface
Implementation / Coding
Traceability Matrix
Integration Testing
Integration Testing Attachment
Installation Testing
Boundary Testing
Boundary Testing Attachment
Error Testing
Error Testing Attachment

Jeannet Moldenhauer is a senior quality assurance/regulatory affairs professional at Vectech Pharmaceutical Consultants, located in Farmington, Michigan. She has an extensive background in the development and management of a variety of sterilization and validation processes in the healthcare industry. She has a proven track record of

successful NDA, sNDA, AADA and DMF submissions to the US Food and Drug Administration (FDA), with special expertise in the rehabilitation of companies with negative FDA findings, restoring them to compliance. Additionally, she has substantial experience in assessing and validating laboratory and production facilities in need of solutions for regulatory purposes.

COMPLIANCE SOFTWARE SOLUTIONS CORP.

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21 CFR Part 11 Compliance Assessment

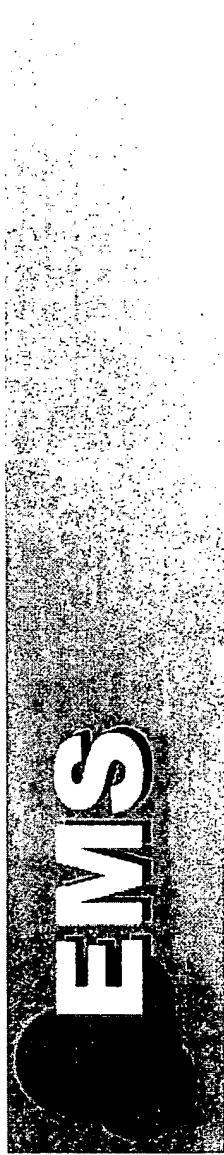
Compliance Software Solutions Corporation (CSSC) has developed the Environmental Monitoring Software System (EMSS[®]), Version 2.2.1 to comply with the requirements defined in the FDA's 21 CFR Part 11 for Electronic Documents. The EMSS is a closed system designed to ensure accuracy, reliability, and consistently intended performance. As established in the regulation, EMSS incorporates the following:

Requirement	EMSS Assessment
Validation	CSSC offers a software validation package for the system. It includes documentation of the implementation and coding, traceability analysis, integration testing, installation testing, boundary testing, and Y2K testing.
Audit Trails	The independent and non-modifiable Audit function provides for secure, computer-generated date and time stamp of record changes and key operator entries and activities. Actions that review, create, modify or delete records are retained for viewing and / or printing. Reports can be generated for each facility by date range and specific table (audit record).
System Security	System access is limited to authorized and qualified users as established in the Security database. There are five levels of security in the EMSS, each providing the appropriate and necessary access to the required functions of Administrators, Managers, and QA / QC Users. A No Access level allows for an individual's name to be included in a drop down menu without affording that user login capability. Additionally, a separate Read-only access application is available for generating reports. The EMSS has a log out security feature, which is automatically activated once the pre-set period of time (3 – 30 minutes in one minute increments) has been met. This ensures that should a workstation be left unattended, an unauthorized individual cannot access the application.

Requirement	EMSS Assessment
Password Maintenance	<p>The EMSS provides for initial and periodic testing, as well as a user defined password expiration interval. Password expiration dates are defined and set by the Administrator (from 10 – 90 days in 5 day increments). Only the Administrator has access to Security Maintenance.</p> <p>Once a password expires, it can never be reused. Passwords can be alpha numeric, and must be 6 to 8 characters.</p>
Record Retention, Protection, Retrievability, and Reproducibility	<p>The EMSS has been designed and tested to accurately retrieve and generate all reports and database records. All electronically stored records are validated to be able to be accurately generated, retained, protected, and readily retrieved in both "human readable and electronic form" throughout the retention period. A validated archive and unarchive feature further adds to the record retention and reporting capability.</p>
Operational Checks	<p>Where necessary, the appropriate operational checks have been put in place to enforce step and event sequencing. The system will only allow events to be performed in the appropriate sequence. It is not possible to perform certain steps before others are complete.</p>
Authority Checks	<p>Only authorized personnel have access to the application, and the ability to use the system. User Maintenance / Security level access is set by the system Administrator. Each level of security has unique, restricted access to the system.</p> <p>The EMSS has built-in security protection that does not allow a user to make more than five attempts to log into the system. After the third unsuccessful attempt to login, the user is "locked out" of the EMSS and only the system Administrator can reactivate the user.</p>
Device Checks	<p>Only terminals with the EMSS installed can make data modifications / entries. This ensures the validity of the source of the data input and / or operational instruction.</p>

Requirement	EMSS Assessment
Documentation Controls	A single copy of all system documentation is provided with the site license.
Electronic Signature Security	Only those users established in the security database that have been granted access to the EMSS can login. Attempting to enter an incorrect password three times will lock the user ID out of the system. Only the Administrator will then be able to unlock that user ID.
Password Security	Controls ensure the security, integrity, and uniqueness of the identification and password combination used for login and electronic signature. Passwords must be between 6 and 8 characters. Each password is unique. Two users cannot have the same password. Passwords are always displayed as asterisks.
Electronic Signature Assignment	Each user's unique electronic signature cannot be reused or reassigned to another user. Each user name and password is unique. Once a password expires it can never be reused again by anyone.
Electronic Signatures Not Based Upon Biometrics	<p>Both a user name and password are required for initial login. Both are required on subsequent logins when security logoff has occurred due to inactivity in the EMSS.</p> <p>In order to perform reviews, additions, deletions, or modifications to any records, the authorized user is required to authenticate their identity by signing into the function and re-entering his or her password. The activity performed is then captured in the audit trail, and a full manifestation of that individual's name will appear in the audit record.</p>
Electronic Signature With Biometric Links	The system is designed to preclude use by anyone except a genuine user. If an individual is not established in the User Maintenance database there is no ability to access the EMSS.

Requirement	EMSS Assessment
Name Display	The printed name of the individual who signs a record electronically is always clearly displayed. His or her user name will appear on relevant documents and reports generated by the system. The user ID of the individual logged into the EMSS is displayed on the lower task bar of the application window.
Signature Purpose	The meaning of each electronic signature, as defined by the individual organization, must be coupled with the appropriate procedures and training.
Signature Binding	Electronic signatures cannot be cut, or copied and pasted, or transferred by any means. The EMSS does not allow user names to be "auto-filled" into fields. Where required, those names established in the User Maintenance database can be entered in fields by means of the drop down menu.



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Criteria for an Effective Environmental Monitoring Program*

The EMSS©

- Date and Time of Test
- Test Method/Procedure Reference
- Activity Level at Site During
- Equipment Identification
- Location
- Area Classification
- Schematics of Area Showing Sample Site Locations
- Sample Site (Critical and Non-Critical)
- Test Results
- Evaluator of Results
- Date Results Read
- Alert and/or Action Level
- Temperature and Time of Incubation
- Control Test Results
- Certification, Validation, and Expiration Date of Media Used
- Characterization of Contaminants
- Name of Reviewer
- Reporting of Data
- Review of Historical Data
- Change Control System
- Calibration Date on Instrumentation
- Methodology, Analysis Used to Specify Action/Alert Level
- System for Documenting Investigative/Corrective Action
 - 1. Description of Deficiency
 - 2. Possible Cause(s) of Problem
 - 3. Identification of Person Responsible for Relevant Corrective Action
 - 4. Description of Action Steps and Their Schedule for Implementation
 - 5. Evaluation of Effectiveness of Action Steps

EMS

Environmental Monitoring
Software System©

Compliance Software Solutions Corporation (CSSC)

The main menu is used to access all functions of the Environmental Monitoring Software System (EMSS). It displays current status of all test activity. The main menu includes a summary table for all relevant actions for the date selected on the calendar, including information regarding tests initiated and read on that date, test readings due on that date, and test readings past due in the categories of viable tests, non-viable tests, and other tests (i.e. water testing). It also displays the number of open testing deviations currently in need of resolution.

The drop-down menus at the top of the screen provide access to the initiate, update, and maintenance functions, along with documentation, CSSC Internet access and reporting functions. The user may initiate or update an environmental survey, and document a deviation and its investigation. The main menu also permits the user to perform maintenance on the databases outlining the facilities, rooms, test types, test sites, test groups and group assignments, and site codes and descriptions. All the reporting functions are accessed by selecting *Reports* from the upper task bar. Lastly, all support documentation including the System Use SOP for the EMSS, and the IQ, OQ, and PQ document templates are accessed by selecting *Documentation*.

Environmental Monitoring System

Environmental Monitoring System Version 2.21

File: Initiate or Update Environmental Tests, Database Maintenance, Review Reports, Documentation, Help

Environmental Monitoring System

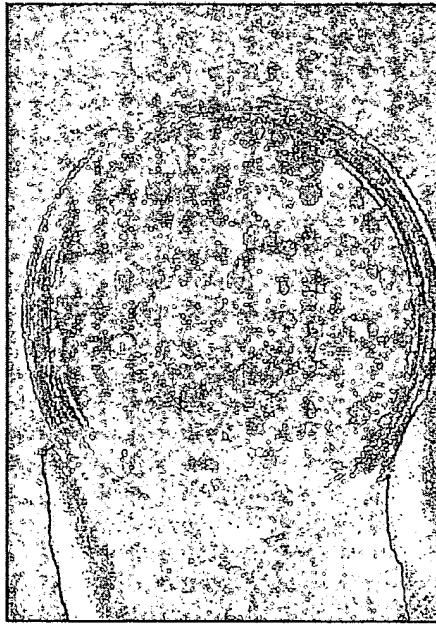
Current Facility

EMS Test Facility

Sun	Mon	Tue	Wed	Thu	Fri	Sat
30	31	1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31	1	2
3	4	5	6	7	8	9

Activity Summary For This Date:

	Viable	Nonviable	Other
Tests Initiated:	0	0	0
Tests Read:	0	0	0
Test Readings Due:	0	0	0
Test Readings Past Due:	15	12	2
Open Deviations:	5	...	



Today Is:	1/16/2002	Current User:	J. Glevinson	EMail OFF
Start	8:21 AM	End	8:21 AM	
File	Open	Print	Print	
Help	Help	Help	Help	

When selecting a date on the calendar, the operator can access other EMSS activities. Double-clicking on the highlighted date brings up the Select Activity form, which presents the user with several options. These include initiating a new survey, updating survey data, updating current test readings, printing survey and test reading worksheets, and an ability to view any and all initiated surveys and readings due. Many of these same functions can be accessed using the *Initiate or Update Environmental Tests* drop-down menu.

The Facility Maintenance, and Room or Area Maintenance screens are accessed through the *Database Maintenance* drop-down menu and selecting *Facility or Rooms / Areas*, respectively. Compliance Software Solutions has chosen Visio® to create all the facility and room / area diagrams in the EMSS. A single user site license for Visio® Standard is provided with the EMSS site license.

Rooms or areas are defined for each facility created in the system. Areas could be used to define general facility parameters or for facility water systems, HVAC systems, etc. The user can perform maintenance on the room / area utilizing the Room or Area Maintenance screen. The room / area information which can be configured by the user includes the room description, room reference number, room and production area classification, and the room diagram itself. Below is a representative screen of a room / area created in Visio®. Note that the system allows for two classifications to be set-up within the same room / area (i.e. Class 100 and Class 10,000). A text table within the EMSS enables the user to personalize their classification drop down menu (i.e. U.S. standards or European standards).

Environmental Monitoring System

Graphical User Interface

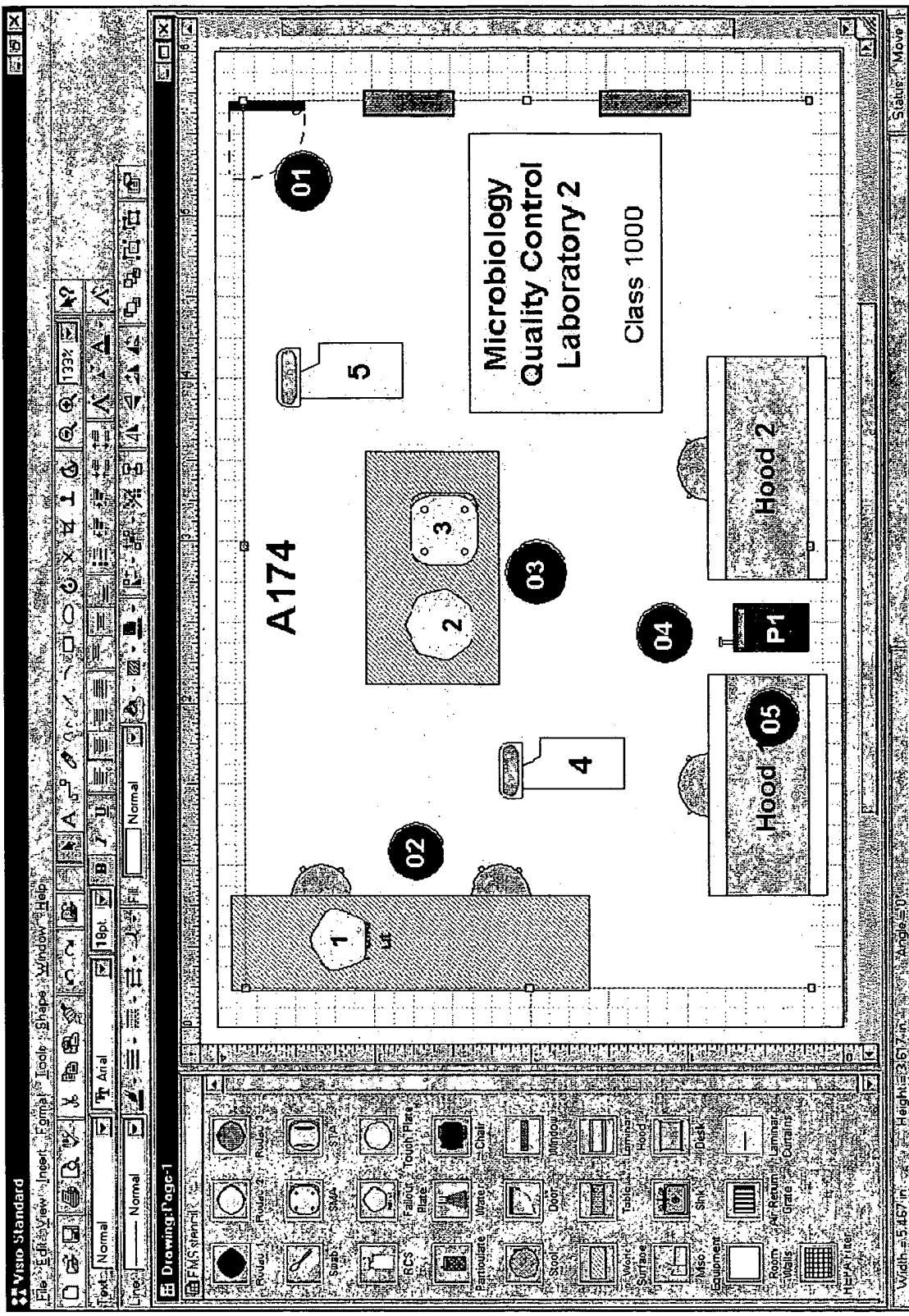
EMS Room or Area Maintenance	
<input type="button" value="Find"/> <input type="button" value="Add New"/> <input type="button" value="Next"/> <input type="button" value="Previous"/> <input type="button" value="Update"/> <input type="button" value="Close"/>	
Room ID: <input type="text" value="5"/> Room Ref No: <input type="text" value="MicroLab2 A174"/>	Facility ID: <input type="text" value="EMS Test Facility"/>
Room Description: <input type="text" value="Micro Lab2 A174"/>	Classification: <input type="text" value="Class 10,000"/> <input type="text" value="Class 1,000"/>
Prod Area: <input type="text"/>	Last Maint Date: <input type="text" value="10/19/1999 2:27:14 PM"/>
Last Maint By: <input type="text" value="GeorgeL"/>	<input type="button" value="ADD"/> <input type="button" value="EDIT"/> <input type="button" value="Delete"/>
Room Diagram:	

Generating or modifying the graphical representations of the facilities and rooms / areas in the system is accomplished by “clicking” on the ADD or EDIT buttons that appear on the maintenance screens. The graphics generated not only document objects within the room, they can also be used to document test sites. These diagrams are displayed on the worksheets, as well as on many of the reports. When the ADD or EDIT buttons are clicked, the current facility, or room diagram opens in Visio®. CSSC has created a custom stencil of recognizable icons to facilitate the creation or modification of the facility and room diagrams. These icons can be easily “clicked” and “dragged” into the facility or room diagram, in order to identify and specify where a particular test is to be performed, or a structure is located.

The templates support a wide variety of predefined tests (i.e. particulate, microbial), as well as user-defined tests (i.e. pH, pressure, chemical).

Environmental Monitoring System

Graphical User Interface



The system has the ability to automatically assign identification numbers to survey test samples. To activate this feature, the operator selects the Auto Assign Survey ID checkbox.

The system also has the capability to require identification for any media lots and equipment utilized in the testing. To activate these features, the operator selects the Require Media Lots / Require Equipment ID checkboxes.

The user may update the facility name, and reference the frequency of a facility's review (re-validation) utilizing the Facility Name and Review Frequency fields respectively.

The periodic review status may be updated utilizing the checkbox on the screen. A facility can be activated by checking the Active checkbox. Inactivating a facility (such as one set up to perform a validation or specific testing) prevents inadvertently changing facilities, and data entry into a facility other than the current production environment.

As with the Room / Area Maintenance, the EMSS assigns a unique ID to every Facility that is created in the database. This ensures that no duplications exist within the program.

EMS

Facility Maintenance

Facility ID: Facility Status: Active

Facility Name: EMS Test Facility

Periodic Review:

Review Freq:

Last Review:

Next Review:

Facility Diagram:

Auto Assign Sample ID

Require Media Lot

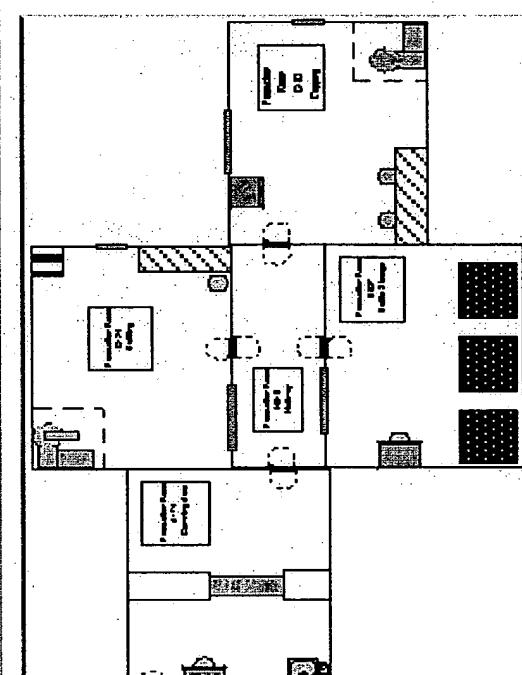
Require Equipment ID's

 Find
 Next
 Previous

 ADD

 EDIT

 Delete



Last Maint Date:

Last Maint By:

Print Function  Print Message 

Print Function  Print Message 

The user can review or perform maintenance on the test site information utilizing the **Test Site Maintenance screen**. The test identification information which can be configured when a site is identified includes the test type, room identification, site type, site classification, test site description, reference SOP, user reference number, the alert and action limits, and any comments associated with that site.

The **Test Identification Maintenance screen** may be accessed by utilizing the **Database Maintenance** drop-down menu and selecting **Test Site Identification**.

To enhance comprehension of the test procedure a site picture and / or site video can be embedded in the software and viewed on this screen. The video clip not only provides a visual representation of the referenced procedure, it also facilitates identification of the site and potentially minimizes operator error.

Environmental Monitoring System Graphical User Interface

EMS Test Site Identification Maintenance

Test Identification

Test ID: 3 Facilitor: EMS Test Facility Production Lot Specific:

Test Type: Rodac TGA Plate Micro Lab2 A174

Room ID: Micro Lab2 A174

Test Site Description: Floor between workstations approx 2 feet in front of work table.

Test Ref SOP:

Test User Ref:

Alert and Action Limits

Action Limit: 6

MAX: 4 MIN: 0

One Side

Site Classification and Type

Site Classification: Class 1UUUU

Site Type: Floor

Site Picture  ADD Delete

Site Video  ADD Delete

Last Maint Date: 10/7/1999 11:53:08 AM

Last Maint By: George

Memo:

Both the Test Group Maintenance and Group Assignments functions can be accessed by utilizing the *Database Maintenance* drop-down menu and selecting *Test Groups* or *Group Assignments*, respectively.

The user can establish groups based on the frequency with which specific tests are performed. Once the groups are set, and the rooms / areas and sites within those rooms are defined, tests can be assigned to a desired group (frequency). If all the test sites in a specific room are part of a specific group, they can all be selected by using the *Select All* button. The *Remove All* button will uncheck all those boxes that are selected.

Test sites are selected individually by clicking on the checkbox adjacent to each location description for the current room.

EMS Test Group Maintenance

Group ID:	<input type="text" value="2"/>	Group Description:	<input type="text" value="Weekly Tests"/>
Frequency:	<input type="text" value="Weekly"/>	Lot Specific	<input type="checkbox"/>
Inactive Status	<input type="checkbox"/>		

Last Maint Date:	5/31/2001 11:51:31 AM
Last Maint By:	george!

Group Assignments

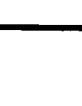
ENVS Group Assignments		Select the Test Group							
		Weekly Tests							
<table border="1"> <tr> <td>Select Room or Area</td> <td>Check Tests in Group</td> </tr> <tr> <td> <input type="checkbox"/> Micro Lab 1 <input type="checkbox"/> Micro Sterility Suite <input type="checkbox"/> Micro Growing Area <input type="checkbox"/> Production Room 208 Lyophilization <input type="checkbox"/> Production Room 207 Tablet Molding <input type="checkbox"/> Production Room 208 Packaging <input type="checkbox"/> Production Room 205 Raw Material Sto <input type="checkbox"/> Production Room 100 Personnel Prep A <input type="checkbox"/> Production Room 101 Growing Area <input type="checkbox"/> Production Room 102 Bottling Stage <input type="checkbox"/> Production Room 103 Bottling <input type="checkbox"/> Production Room 104 Capping <input type="checkbox"/> Water System <input type="checkbox"/> New Room Name 1 <input type="checkbox"/> New Room Name 2 </td> <td> <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input checked="" type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 </td> </tr> <tr> <td colspan="2"> STANDARD TESTS <input type="checkbox"/> Floor site in doorway - room entrance. <input type="checkbox"/> Floor site in front of laminar flow hood. <input type="checkbox"/> Floor site in doorway - to sterility suite. <input checked="" type="checkbox"/> Floor site in front of sink. <input type="checkbox"/> Floor site in center of room. <input type="checkbox"/> Site on work surface of laminar flow hood <input type="checkbox"/> Swab sample within sink 1. <input type="checkbox"/> Swab sample within sink 2. <input type="checkbox"/> Fallout plate within laminar flow hood. <input type="checkbox"/> Touch plate taken on work surface. Airborne contamination count taken in center of room. </td> </tr> <tr> <td colspan="2"> DETAILED TESTS <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10 <input type="checkbox"/> 11 <input type="checkbox"/> 12 <input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23 </td> </tr> </table>		Select Room or Area	Check Tests in Group	<input type="checkbox"/> Micro Lab 1 <input type="checkbox"/> Micro Sterility Suite <input type="checkbox"/> Micro Growing Area <input type="checkbox"/> Production Room 208 Lyophilization <input type="checkbox"/> Production Room 207 Tablet Molding <input type="checkbox"/> Production Room 208 Packaging <input type="checkbox"/> Production Room 205 Raw Material Sto <input type="checkbox"/> Production Room 100 Personnel Prep A <input type="checkbox"/> Production Room 101 Growing Area <input type="checkbox"/> Production Room 102 Bottling Stage <input type="checkbox"/> Production Room 103 Bottling <input type="checkbox"/> Production Room 104 Capping <input type="checkbox"/> Water System <input type="checkbox"/> New Room Name 1 <input type="checkbox"/> New Room Name 2	<input type="checkbox"/> 13 <input type="checkbox"/> 14 <input type="checkbox"/> 15 <input checked="" type="checkbox"/> 16 <input type="checkbox"/> 17 <input type="checkbox"/> 18 <input type="checkbox"/> 19 <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 21 <input type="checkbox"/> 22 <input type="checkbox"/> 23	STANDARD TESTS <input type="checkbox"/> Floor site in doorway - room entrance. <input type="checkbox"/> Floor site in front of laminar flow hood. <input type="checkbox"/> Floor site in doorway - to sterility suite. <input checked="" type="checkbox"/> Floor site in front of sink. <input type="checkbox"/> Floor site in center of room. <input type="checkbox"/> Site on work surface of laminar flow hood <input type="checkbox"/> Swab sample within sink 1. <input type="checkbox"/> Swab sample within sink 2. <input type="checkbox"/> Fallout plate within laminar flow hood. <input type="checkbox"/> Touch plate taken on work surface. 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To initiate a test by room / area or test ID, the user selects *Initiate Test → By Room / Area or Test ID* from the *Initiate or Update Environmental Tests* drop-down menu. This action will bring up the *Initiate Test By Room or Test ID* screen, which allows the user to initiate an environmental survey according to its room location or its individual test ID. This is typically used for sites to be tested that are not part of a specific group (e.g. retesting a site as a result of an excursion, or an infrequently tested site). Group Tests can be initiated in a similar manner off the same task bar function, as well as by double clicking on the highlighted date on the main menu and choosing the *Initiate EMS Survey* radio button and clicking *Continue*.

After the test(s) has been selected, the user is prompted for personnel identification, product code, lot number, and shift information on Survey screen. The user may then direct the EMSS to generate the documentation required to perform the selected test(s) by clicking on the *Initiate* button. The system can be set to display a preview of the Survey Worksheet. The user may print the generated worksheets by clicking on the print button. The printed worksheets are used by the Technician to record all pertinent sampling information.

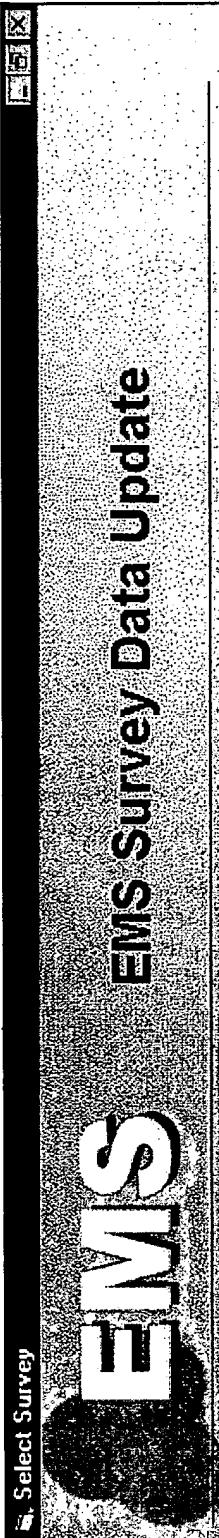
The user can also elect to have bar code labels printed for the tests outlined on the Survey Worksheet. Bar codes provide an effective and efficient means of identifying samples. The bar code labels that are generated by the EMSS are typically printed on a laser printer on a standard self-stick Avery® label stock. A wedge or wand type bar code reader is used to scan these labels when plates are scheduled to be read from the lab.

Print Worksheet

1 of 1     <img alt

In order to select the survey to be updated from the worksheets, the user selects the *Record Survey Data* radio button from the *Select Activity* menu accessed by double clicking the highlighted date on the calendar.

The user can view All OPEN surveys or All Surveys for a given date or date range. Highlighting the desired Survey # and clicking *Select*, will open that survey update form.



EWS Survey Data Update

Select Survey To Record Sampling Data.

Once a particular survey is selected from the EMS Survey Data Update screen, the Survey Data Entry / Update screen opens, and displays a drop down menu for each of the rooms included on the survey, as well as a drop down for each test type in that room on that survey (i.e. Rodac TSA Plates, Non-Viable Particulate, etc.). Selecting from these two drop down menus will display all the survey data fields for that test type and room in the table below.

The user is prompted in the **Status** column to enter the required data in the appropriate field for that specific row (e.g. Sample Date/Time, Sample By, On Test Date/Time, etc.). Sample ID's are assigned a unique number if this feature has been selected for the current facility.

The **Media Lot number** (if applicable), and the **Equipment ID** fields are selected utilizing the drop-down menus in the individual fields. Only those media lots or equipment "flagged" as being within the expiration date or calibration date in the Media Growth Promotion Test and Equipment Calibration Data tables will be displayed on the drop down. The maintenance for these fields is accessed from the main screen database / maintenance drop down menu, and selecting **Media Growth Promotion Test** or **Equipment Calibration Data**. Equipment ID's and Media Lots can be defaulted to a single selection by utilizing the **Edit Equip ID's** or **Edit Media Lots** buttons, respectively.

A "No Test" may be recorded for a particular sample by clicking on the **No Test** button on the screen. If the survey result is a **No Test**, the system will prompt the user for an explanation via the **No Test Confirmation** screen. The individual room in which you are updating data can be viewed at any time by clicking on the **View Room** button. Additionally, **Notes** may be added to the record.

Survey Data Entry/Update

EVS

Survey Data Update

Survey No. 1108
Group Desc: Daily TestsSelect Room/Area
Rooms In 5
SurveySelect Test Type:
 Rodac TSA Plate
 Micro Lab 1 rrRoom Activity Level:
 Static
 Dynamic

Rodac TSA Plate Viable 2

Test ID Ref	Sample Date	Sample By	Sample ID	On Test Date	On Test By	Media Lot	Equipment ID	Status	Sample Date/Time
F5	01/10/02 12:00AM	JRadigan	SC00000394	01/10/02 12:00AM				Not Started	
E1	01/10/02 12:00AM	JRadigan	SC00000404	01/10/02 12:00AM				Not Started	
F2	01/10/02 12:00AM	JRadigan	SC0000026A	01/10/02 12:00AM				Not Started	
F4	01/10/02 12:00AM	JRadigan	SC0000015A	01/10/02 12:00AM				Not Started	
F1	01/10/02 12:00AM	JRadigan	SC0000014A	01/10/02 12:00AM				Not Started	

Test ID Ref	Test ID	Alert Limit	Action Limit	Inc. Hours	24	No Test	View Room
F5	17						EXIT
For it in center of room.			25	30	01/11/02 12:00AM	Note	
Audit Function		Audit Message					

The test reading values may be entered onto the *Test Reading Update* screen. If the value is calculated utilizing the Estimator function the displayed value is noted with a block letter "E". If the test result is a Non Quantifiable (or TNTC) condition, this may be entered into the system by clicking on the *Non Quant* button. The system will prompt the user for confirmation of the non-quantifiable condition, and create a deviation record for that test survey. A *No Test* may be entered for a sample by clicking on the *No Test* button. If the survey results in a *No Test* condition, the system will prompt the user for confirmation using the *No Test Confirmation* screen.

As data is entered, if the alert or action level (displayed at the bottom of the screen) is exceeded for a test, a message is displayed for the operator to acknowledge. If an action limit or alert limit is exceeded, the Action Level Exceeded or Alert Level Exceeded message boxes are displayed, respectively. Each requires confirmation of the excursion condition. The user may confirm the action / alert limit was exceeded for the survey by clicking the *OK* button; the entered number is then written to the EMSS database. If the user selects the *Cancel* button, the active field in the *Test Reading Update* table is "erased" and must be entered again. If an action limit is exceeded and confirmed by the operator, a deviation record is automatically generated for subsequent processing and corrective action. A deviation can also be manually generated when an alert limit is exceeded. The EMSS automatically generates and sends an e-mail notification message to the appropriate company personnel notifying them of all aberrant conditions. The EMSS will automatically generate a historical profile for the aberrant site and attaches it to the e-mail notification.

If an alert level is exceeded and confirmed by the operator the entered number is then written to the EMSS database. The EMSS also automatically generates and sends an e-mail "adverse trend" message to the appropriate company personnel notifying them of the aberrant condition. A historical profile is attached to this e-mail message, as well.

The total number of current deviations in need of resolution is displayed on the main menu screen. Deviations must be resolved using the *Test Deviation Investigation* form accessed from the main menu *Initiate or Update Environmental Tests*.

The user can access the *Test Deviation Investigation* screen by utilizing the *Initiate or Update Environmental Tests* drop-down menu and selecting *Update Deviation Investigation*.

A deviation record is automatically generated in the event the results of the survey exceed the relevant testing limits. Following any investigation into the details of the deviation in question, the corrective actions and final conclusions are documented in order to resolve the deviation.

The *Test Deviation Investigation* screen contains tabs for *Investigation details*, *Identification (morphology)* details, *Actions narrative*, and *Conclusions* reached as a result of the deviation investigation.

The user can scroll through all existing deviation records by utilizing the Next / Previous buttons on the right of the *Test Deviation Investigation* screen. The EMSS automatically retrieves all pertinent information for the current deviation and displays this in the *General* tab.

The checkboxes (user created) on the left side of the *Investigation* tab along with the text box on the right are used to describe in detail the particulars of the investigation

The *Actions* tab contains a text box, which may be used to enter the description for the actions taken.

The *Conclusions* tab may be used to describe the final conclusions for the deviation and its resolution status using the Close checkbox. Identification of the individual resolving the deviation, as well as the date and time of its resolution, must also be specified.

EMS Deviation Investigation and Conclusions



Test Deviation Investigation

Deviation Control #: 2014
Test ID: 45 Facility: Test EMS Facility

Room ID: 6 Micro Sterility Suite

Test Type: 5 Non Viable Particulate

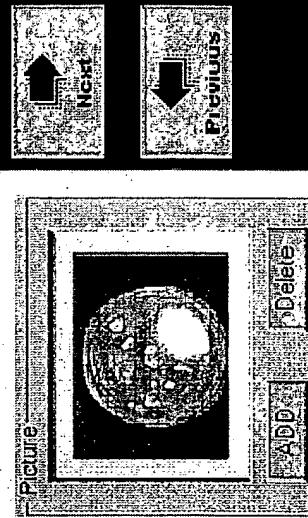
Prod Lot: 0ui0iu0 Media: Equipment:

Test Date: 8/5/1999 Test By: T Joyce Sample ID: +S04109A

Read Date: 8/5/1999 Read By:

Action Limit: 5 Reading: 7

Alert Limit: 2 One Sided



Investigation

Identification

Actions

Conclusions

Investigation Performed

- Check Main Log
- Check Cleaning Log
- Review Batch Record Data
- Verify Training, Records
- Review Other OQC Cond
- Check Utilities
- Other

A review of all documents indicated no possible cause. No deviations from operational or cleaning procedures were found.

Exit

If applicable, results for Gram Stain procedures performed can be captured, along with the identification of the organism(s) genus and species on the *Identification* tab; macroscopic organism morphology characteristics may also be recorded. The organism morphology drop down menus on the Identification tab can be created by the user from the *Text Support Tables* accessed from the *Database Maintenance / Review* drop down.

EMS Deviation Investigation and Conclusions



Test Deviation Investigation

Deviation Control #: 2014 Facility: Test EMS Facility

Test ID: 45 Particulate count taken in room center.

Room ID: 6 Micro Sterility Suite

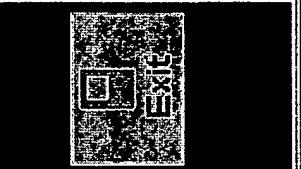
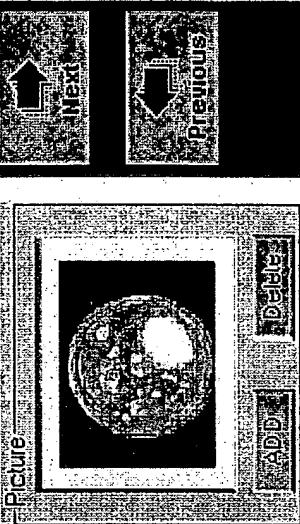
Test Type: 5 Non Viable Particulate

Prod Lot: ouioiouo Mod: Equipment:

Test Date: 8/5/1999 Test Dy: T Juyue Sample ID: +S04109A

Read Date: 8/5/1999 Read By: Reading: 7

Action Limit: 5 One Sided



Status: Open

Investigation: Observed Morphology

DBS: 106.2 Obs: 3

Report No: 102A45 Equipment ID: 999-A123

Observed Morphology: Elevation: Surface texture: Watchdog Report: Equipment ID: 999-A123

TSA: Transparent Depressed Bumpy Layered N/A. Pink Small

Gram Stain: Microscopic Bacteria Yeast Fungi Virus Other

Pos: rod Bacteria Yeast Fungi Virus Other

Identification: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Conclusion: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Action: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Comments: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Report: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

Print: Vitek Gram Stain Microscopic Bacteria Yeast Fungi Virus Other

The Environmental Monitoring System includes a complete reporting package for presentation, analysis, and review of all input test survey data, all relevant testing detail, and database listings information, as well as a wide variety of reports summarizing analyzed and processed surveys.

The Management Reports include a trend analysis package that can retrieve data from a selected time period for presentation and review on demand. This is useful for internal reviews, customer / client audits, regulatory inspections, etc.

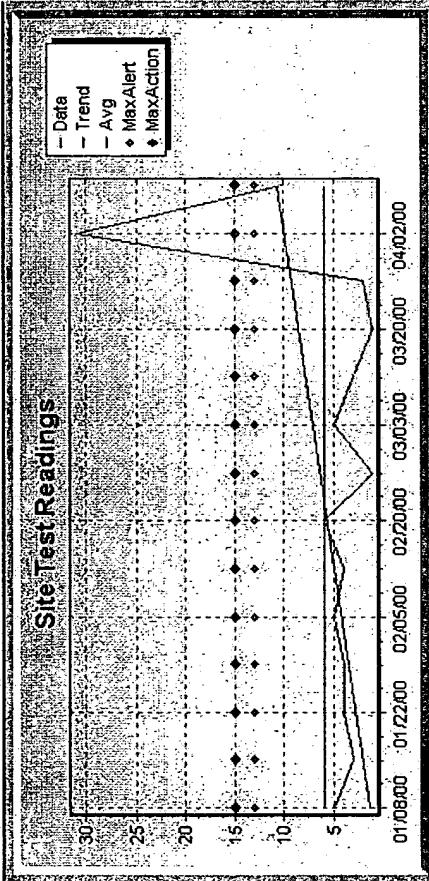
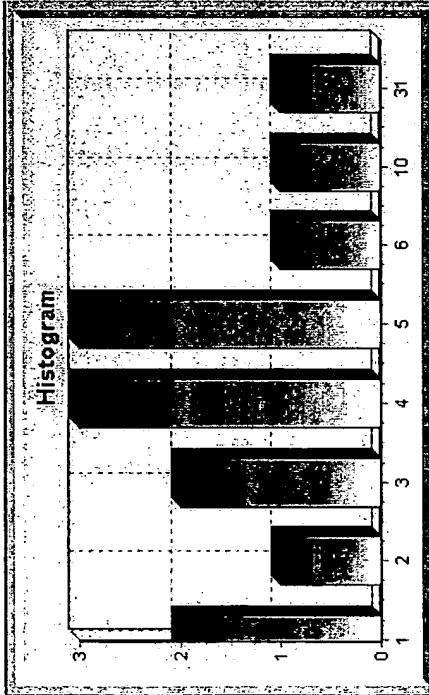
111

Test Site Data Graphs

Room: Micro Lab 2 A174

Test Site: **Floor in center of room.**

Test



Survey Results for Period						
Test Date	Survey ID	Shift	Product Lot	Test By	Sample ID	Read Date
1/8/2000 6:30:04 PM	1039	1		Joyce	+S0690AA	1/15/2000 9:26:04 PM
1/15/2000 10:30:05 PM	1040	1		Georgel	+S0694EA	1/23/2000 12:36:05 AM
1/22/2000 5:30:05 PM	1041	1		Georgel	+S0698EA	1/29/2000 8:29:05 PM
1/25/2000 11:30:05 PM	1042	1		Georgel	+S0102AA	2/2/2000 2:14:05 AM
2/5/2000 10:30:05 PM	1043	1		JFadijan	+S0106EA	2/13/2000 12:56:05 AM
2/10/2000 10:30:05 AM	1044	1		JTR	+S0110EA	2/17/2000 1:30:05 PM
2/20/2000 4:30:05 AM	1045	1		JTR	+S0115EA	2/27/2000 5:55:05 AM
2/23/2000 9:30:05 PM	1046	1		Georgel	+S0119EA	3/1/2000 10:34:05 PM

A screenshot of a software application's menu bar. The 'Edit' menu is open, showing options: Undo, Redo, Cut, Copy, Paste, Delete, Select All, Find, Find Next, Find Previous, Replace, and Exit. The 'Exit' option is highlighted with a yellow background and a black border.

10

Routine organism identification data can be retrieved and displayed to reveal frequencies and trends. Organisms added to the genus / species drop down menu created by the user can be "flagged" as objectionable. When identified, the EMSS will treat this as an excursion, and generate an e-mail along with the corresponding document for the site.

Routine Organism Summary

REIMS

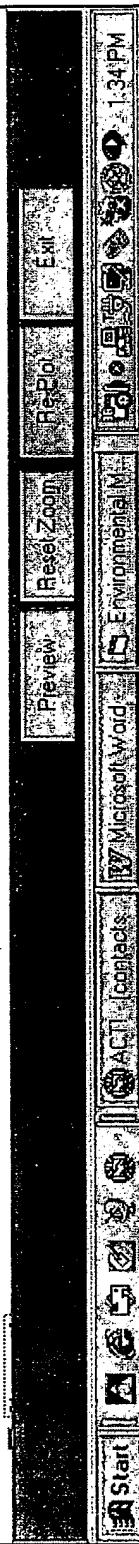
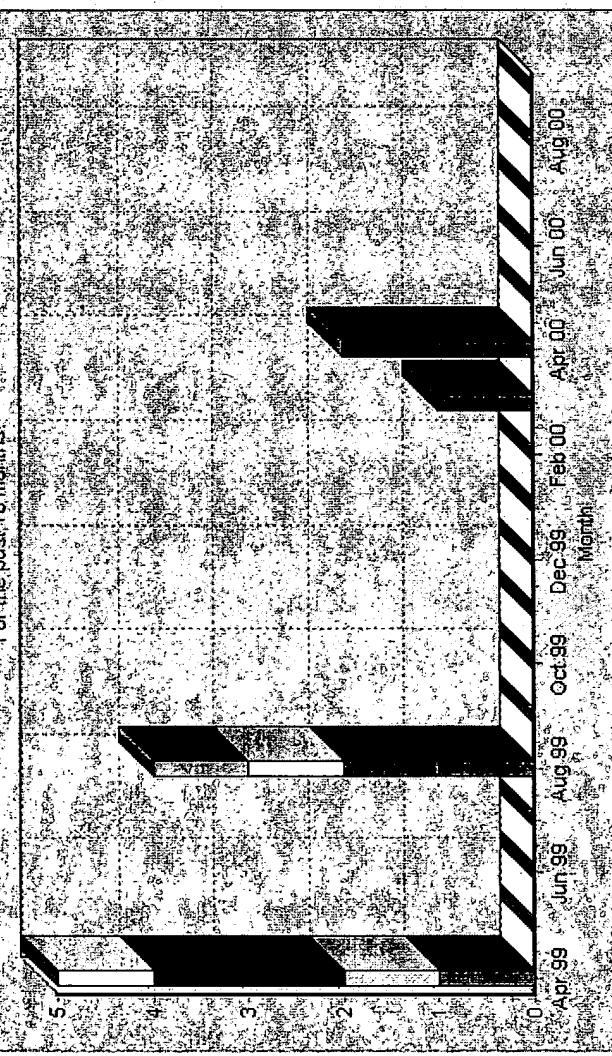
Micro Organism Summary



Routine Organism Identification Summary

For the past 18 months

<input checked="" type="checkbox"/>	Bacillus cereus
<input checked="" type="checkbox"/>	Bacillus circulans
<input checked="" type="checkbox"/>	Bacillus coagulans
<input checked="" type="checkbox"/>	Bacillus steatothermophilus
<input type="checkbox"/>	Clostridium acetobutylicum
<input checked="" type="checkbox"/>	Mold/NOID



1:34 PM

The EMSS meets the electronic records and electronic signature requirements of 21CFR Part 11. Some of the EMSS features include a required logon using a valid user name and password; multiple levels of security with defined access to the application; passwords that expire and can never be reused again; lock out feature preventing unauthorized access to the program; time out feature logging off the user during a defined period of inactivity; full featured, independent, non-modifiable audit trail; and sign in required to perform additions, deletions, modifications, and reviews of all records.

Electronic Signature Confirmation

Electronic Signature Confirmation

User ID:

User Name:

Password:

Action:

Note:

Confirmation of this data maintenance signifies that you have authorized these changes and your electronic signature will be recorded for data modifications/updates.

The independent and non-modifiable Audit function provides for secure, computer-generated date and time stamp of record changes and key operator entries and activities. Actions that review, create, modify or delete records are retained for viewing and / or printing. Reports can be generated for each facility by date range and specific table (audit record).

■ Select Audit Table

Select Table to View

Deviations

Date Range

Start Date: 1/1/2002

End Date: 1/16/2002

Current Facility: EMS Test Facility

Change Current Facility

■ Select Facility

Facility ID	Facility Name
2	EMS Test Facility
3	Test QA/QC Facility
4	Test Validation
8	Test ABC Facility
9	New Water Facility
10	EMS Test Facility 2
15	New Test Facility
16	New Facility Name
18	New Copy Test Facility Name

OK Cancel

The recent annual upgrade to the EMSS included several new special processing features for establishing test types. In addition to the USP model for Water Conductivity, test results can be captured for sites requiring two readings (e.g. samples that are incubated at two temperatures and incubation times), and multiple readings (e.g. particulate samples).

Two Readings											
Selected Sample ID: +S01685A											
<input type="radio"/> Selected Reading	<input checked="" type="radio"/> None										
<table border="1"><tr><td colspan="2">First Reading</td><td>Date / Time</td><td>Read By</td></tr><tr><td>Reading 1</td><td>22</td><td>11 / 3 /2000 8:00 AM</td><td>VGalliani</td></tr></table>				First Reading		Date / Time	Read By	Reading 1	22	11 / 3 /2000 8:00 AM	VGalliani
First Reading		Date / Time	Read By								
Reading 1	22	11 / 3 /2000 8:00 AM	VGalliani								
<table border="1"><tr><td colspan="2">Second Reading</td><td>Date / Time</td><td>Read By</td></tr><tr><td>Reading 2</td><td>16</td><td>11 / 4 /2000 8:00 AM</td><td>VGalliani</td></tr></table>				Second Reading		Date / Time	Read By	Reading 2	16	11 / 4 /2000 8:00 AM	VGalliani
Second Reading		Date / Time	Read By								
Reading 2	16	11 / 4 /2000 8:00 AM	VGalliani								
<input type="radio"/> Average of Two Readings: 19											
<input type="radio"/> Selected <input checked="" type="radio"/> Cached											

The multiple readings feature enables the user to capture up to 49 (7 x 7 grid) results for a single sample, and select an average of the total.

In addition, a model was created to collect and calculate air samples, in a standardized unit of measure and volume of air. Samples can be collected in cubic meters, cubic feet, or liters and converted to a single unit of measure for reporting.

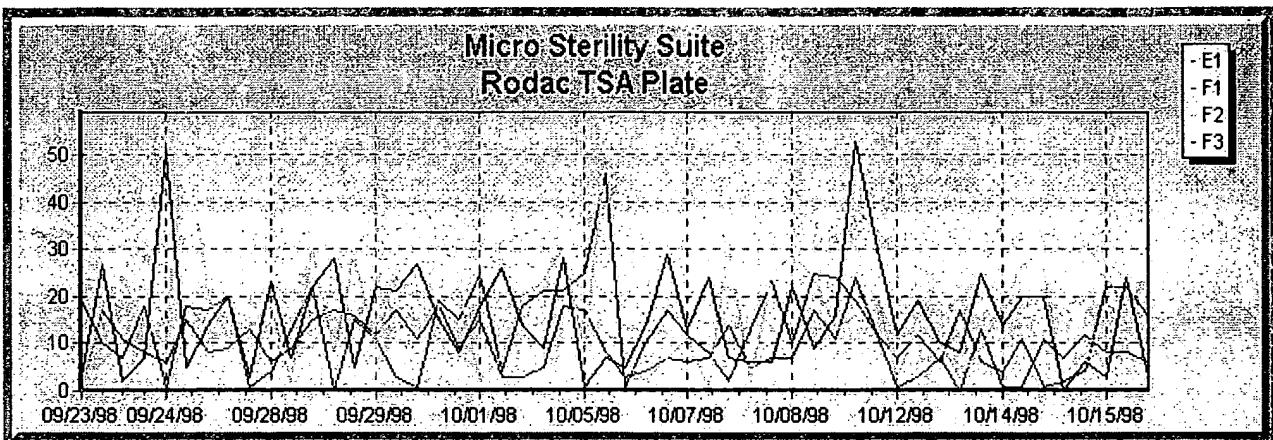
Sample Historical Reports

Environmental Monitoring System

Report Date: October 21, 1999

Historical Test Results By Room and Test ID

Facility EMS Test Facility
Room Micro Sterility Suite



Test ID	User Ref	Test Description	Test Date	Reading	Activity	TNTC	No T st
E1		Site on work surface of laminar flow hood.	9/23/98	0.00	Static	No	No
			9/23/98	17.00	Static	No	No
			9/23/98	11.00	Static	No	No
			9/24/98	8.00	Normal	No	No
			9/24/98	6.00	Static	No	No
			9/24/98	15.00	Static	No	No
			9/25/98	8.00	Static	No	No
			9/25/98	9.00	Static	No	No
			9/25/98	13.00	Static	No	No
			9/28/98	6.00	Normal	No	No
			9/28/98	9.00	Static	No	No
			9/28/98	15.00	Static	No	No
			9/29/98	17.00	Static	No	No
			9/29/98	16.00	Static	No	No
			9/29/98	12.00	Static	No	No
			9/30/98	17.00	Static	No	No
			9/30/98	11.00	Static	No	No
			9/30/98	18.00	Static	No	No
			10/1/98	100.00	Static	Yes	No
			10/1/98	9.00	Static	No	No
			10/1/98	15.00	Static	No	No
			10/2/98	3.00	Static	No	No
			10/2/98	3.00	Static	No	No
			10/2/98	5.00	Static	No	No
			10/5/98	18.00	Static	No	No

Environmental Monitoring System

Historical Test Results By Room and Test ID

Report Date: October 21, 1999

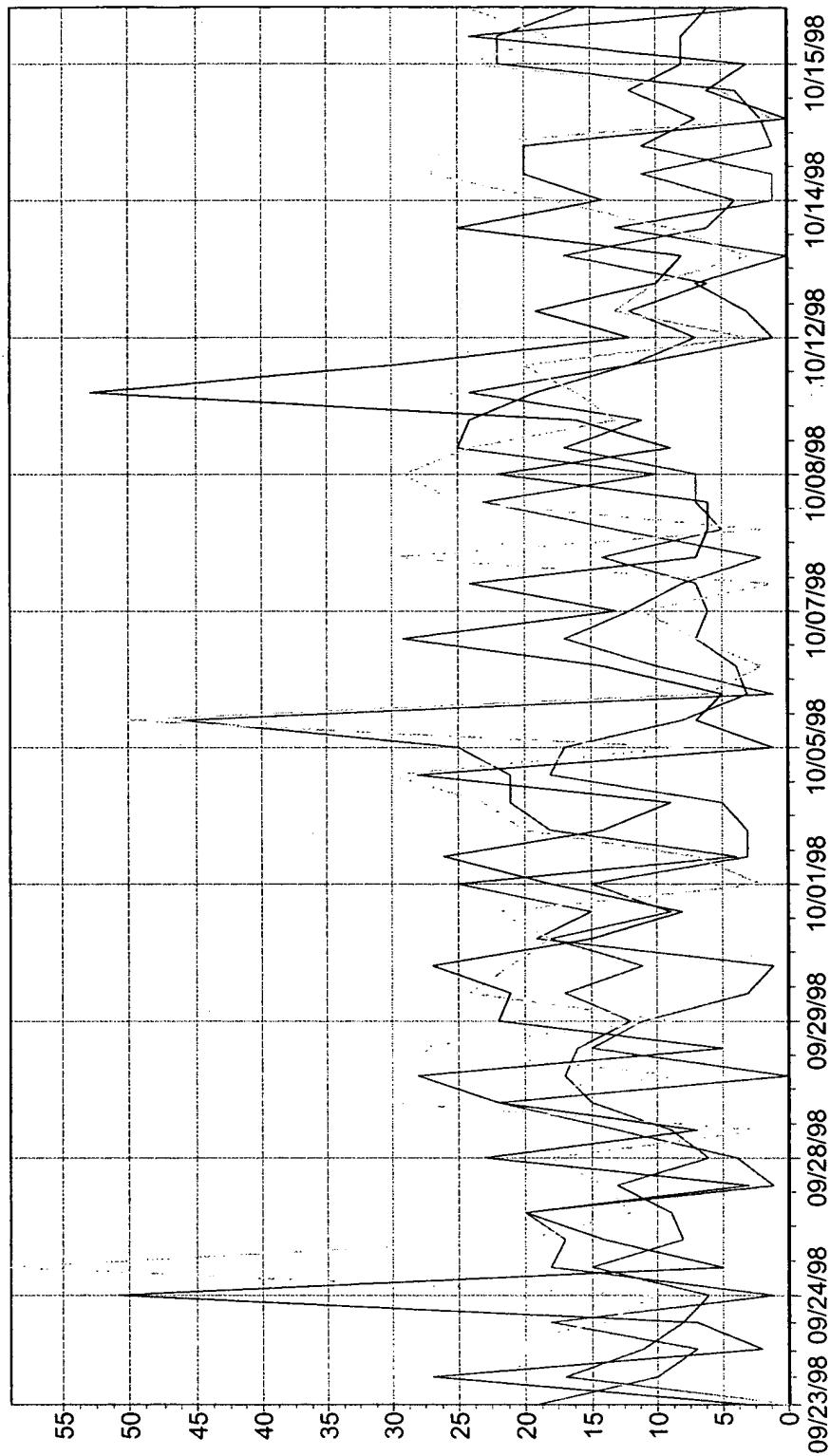
Facility EMS Test Facility Room Micro Sterility Suite

Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
		10/5/98	17.00	Normal	No	No
		10/5/98	8.00	Static	No	No
		10/6/98	3.00	Static	No	No
		10/6/98	4.00	Static	No	No
		10/6/98	7.00	Static	No	No
		10/7/98	6.00	Static	No	No
		10/7/98	7.00	Static	No	No
		10/7/98	14.00	Static	No	No
		10/8/98	5.00	Static	No	No
		10/8/98	7.00	Static	No	No
		10/8/98	7.00	Static	No	No
		10/9/98	17.00	Static	No	No
		10/9/98	11.00	Normal	No	No
		10/9/98	24.00	Static	No	No
		10/12/98	12.00	Static	No	No
		10/12/98	1.00	Static	No	No
		10/12/98	3.00	Static	No	No
		10/13/98	7.00	Static	No	No
		10/13/98	0.00	Static	No	No
		10/13/98	13.00	Static	No	No
		10/14/98	1.00	Static	No	No
		10/14/98	1.00	Static	No	No
		10/14/98	11.00	Static	No	No
		10/15/98	7.00	Static	No	No
		10/15/98	12.00	Static	No	No
		10/15/98	8.00	Static	No	No
		10/16/98	8.00	Static	No	No
		10/16/98	6.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/19/98	10.00	Static	No	No
		10/19/98	15.00	Static	No	No
		10/19/98	1.00	Static	No	No
		10/20/98	3.00	Static	No	No
		10/20/98	7.00	Static	No	No
		10/20/98	15.00	Static	No	No
		10/21/98	1.00	Static	No	No
		10/21/98	4.00	Static	No	No
		10/21/98	10.00	Static	No	No
		10/22/98	18.00	Static	No	No
		10/22/98	6.00	Static	No	No
		10/22/98	4.00	Static	No	No

Micro Sterility Suite

Rodac TSA Plate

- E1
- F1
- F2
- F3



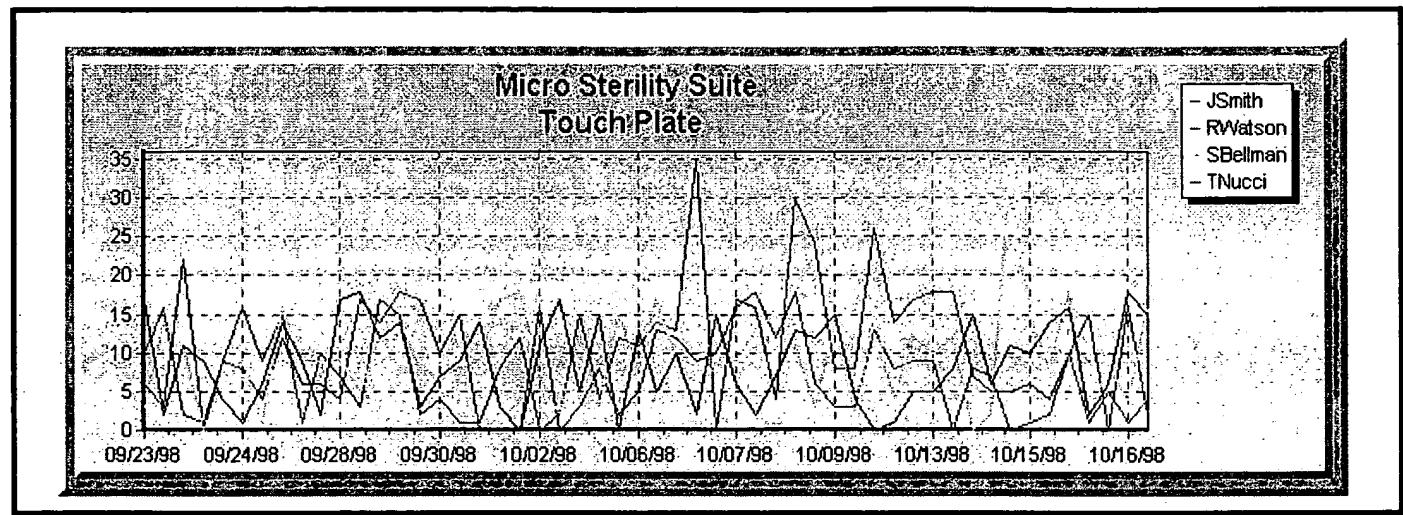
Environmental Monitoring System

Report Date: October 21, 1999

Historical Test Results By Room and Test ID

Facility **EMS Test Facility**

Room **Micro Sterility Suite**



Test ID	User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
	JSmith	Touch plate taken within laminar flow hood.					
			9/23/98	10.00	Static	No	No
			9/23/98	16.00	Static	No	No
			9/23/98	2.00	Static	No	No
			9/24/98	1.00	Normal	No	No
			9/24/98	9.00	Static	No	No
			9/24/98	8.00	Static	No	No
			9/25/98	4.00	Static	No	No
			9/25/98	12.00	Static	No	No
			9/25/98	6.00	Static	No	No
			9/28/98	6.00	Normal	No	No
			9/28/98	4.00	Static	No	No
			9/28/98	17.00	Static	No	No
			9/29/98	14.00	Static	No	No
			9/29/98	18.00	Static	No	No
			9/29/98	17.00	Static	No	No
			9/30/98	10.00	Static	No	No
			9/30/98	0.00	Static	No	Yes
			9/30/98	15.00	Static	No	No
			10/1/98	300.00	Static	Yes	No
			10/1/98	0.00	Static	No	No
			10/1/98	0.00	Static	No	No
			10/2/98	0.00	Static	No	No
			10/2/98	16.00	Static	No	No
			10/2/98	0.00	Static	No	No
			10/5/98	3.00	Static	No	No

Environmental Monitoring System

Historical Test Results By Room and Test ID

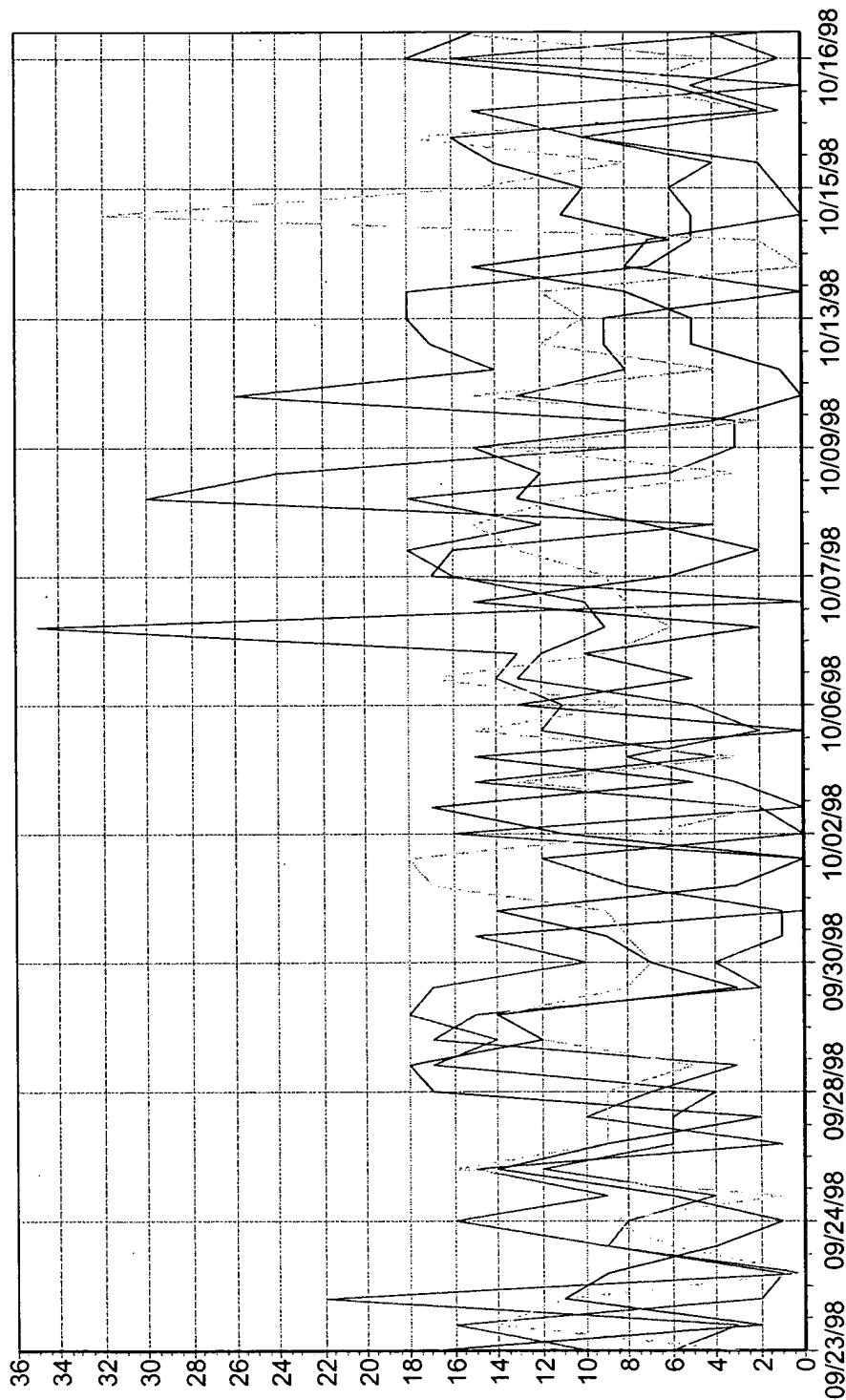
Report Date: October 21, 1999

Facility EMS Test Facility Room Micro Sterility Suite

Test ID User Ref	Test Description	Test Date	Reading	Activity	TNTC	No Test
		10/5/98	8.00	Normal	No	No
		10/5/98	2.00	Static	No	No
		10/6/98	5.00	Static	No	No
		10/6/98	13.00	Static	No	No
		10/6/98	12.00	Static	No	No
		10/7/98	9.00	Static	No	No
		10/7/98	10.00	Static	No	No
		10/7/98	16.00	Static	No	No
		10/8/98	18.00	Static	No	No
		10/8/98	12.00	Static	No	No
		10/8/98	300.00	Static	Yes	No
		10/9/98	18.00	Static	No	No
		10/9/98	6.00	Normal	No	No
		10/9/98	3.00	Static	No	No
		10/12/98	3.00	Static	No	No
		10/12/98	13.00	Static	No	No
		10/12/98	8.00	Static	No	No
		10/13/98	9.00	Static	No	No
		10/13/98	9.00	Static	No	No
		10/13/98	0.00	Static	No	No
		10/14/98	8.00	Static	No	No
		10/14/98	7.00	Static	No	No
		10/14/98	0.00	Static	No	No
		10/15/98	1.00	Static	No	No
		10/15/98	2.00	Static	No	No
		10/15/98	10.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/16/98	5.00	Static	No	No
		10/16/98	1.00	Static	No	No
		10/19/98	4.00	Static	No	No
		10/19/98	13.00	Static	No	No
		10/19/98	3.00	Static	No	No
		10/20/98	17.00	Static	No	No
		10/20/98	4.00	Static	No	No
		10/20/98	1.00	Static	No	No
		10/21/98	300.00	Static	Yes	No
		10/21/98	5.00	Static	No	No
		10/21/98	5.00	Static	No	No
		10/22/98	12.00	Static	No	No
		10/22/98	7.00	Static	No	No
		10/22/98	8.00	Static	No	No

Micro Sterility Suite Touch Plate

— JSmith
— RWatson
— SBellman
— TNucci



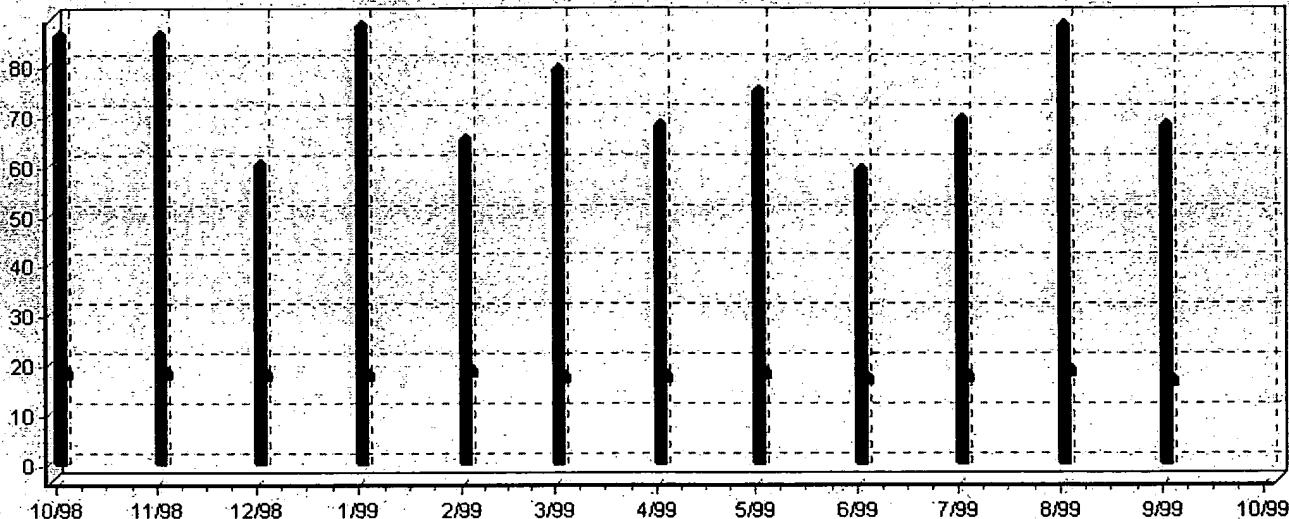
Environmental Monitoring System

Test Type Summary By Room

12 Month Summary for Rodac TSA Plates in Micro Lab 1

Facility: EMS Test Facility

Rodac TSA Plates in
Micro Lab 1
Min/Max Values By Month



Min, Max, Average and number of Surveys (excludes No Test and TNTC or Non Quantifiable readings)

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Min	0	0	0	0	0	0	0	0	0	0	0	0	0
Max	85	85	59	87	64	78	67	74	58	68	87	67	
Avg	17.42	17.27	16.82	16.96	17.87	16.51	16.51	17.44	16.23	16.57	17.65	15.58	
Count	379	354	400	359	346	388	382	362	379	380	377	276	

No Test Summary

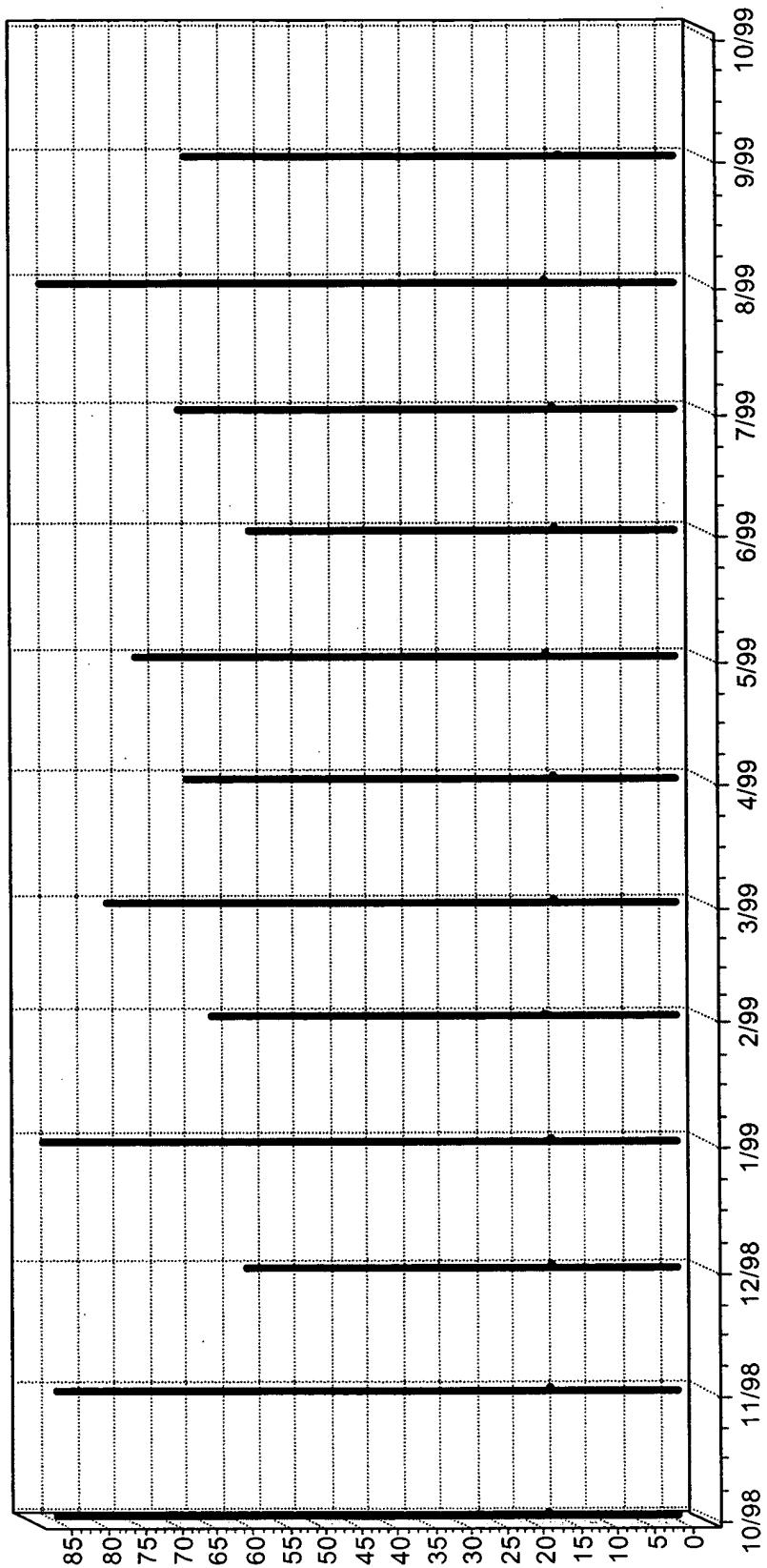
	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Count	7	10	1	6	5	7	7	6	2	7	6	8	

Alert and Action Limit Excursions

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
>Alert	66	57	67	52	75	67	70	68	64	62	67	43	
>Action	31	30	38	32	30	34	26	30	30	26	35	18	
OK	292	281	308	288	250	306	293	274	300	301	288	219	

Rodac TSA Plates in Micro Lab 1

Min Max Values By Month

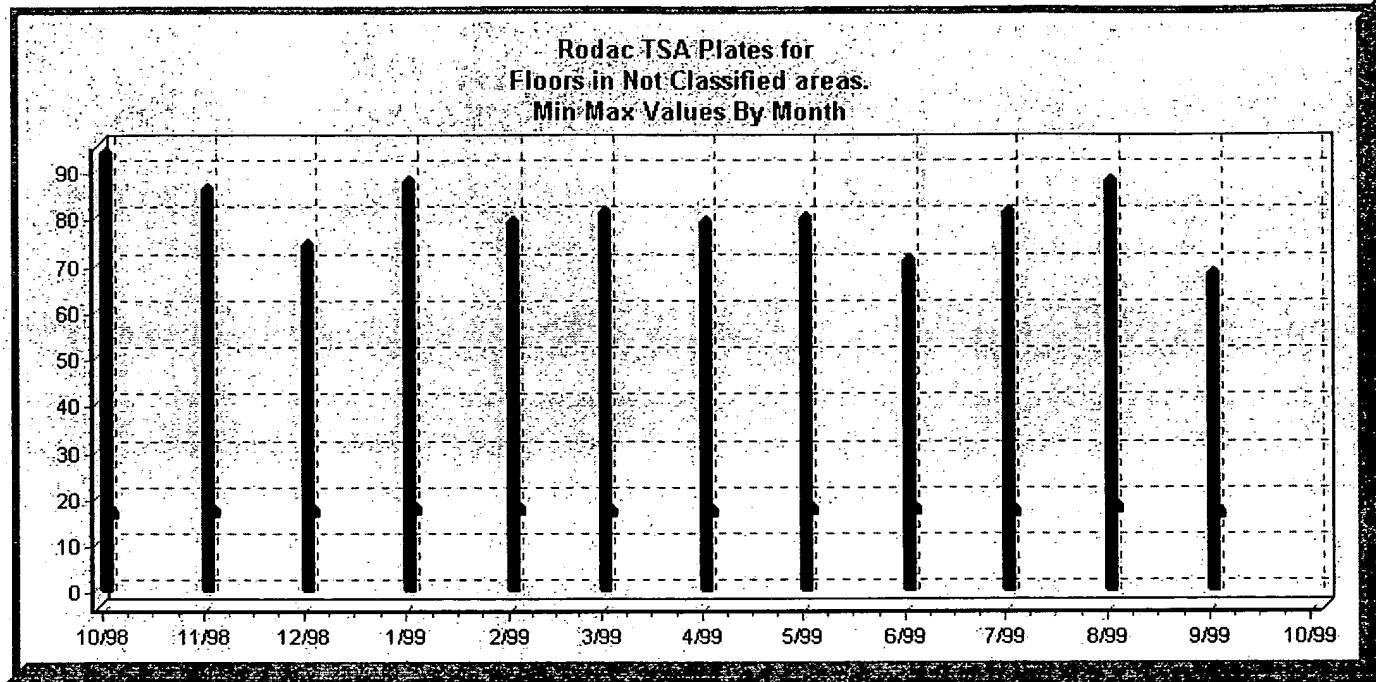


Environmental Monitoring System

Test Site Summary By Test Site and Classification

12 Month Summary for Rodac TSA Plates for Floors in Not Classified areas.

Facility: EMS Test Facility



Min, Max, Average and number of Surveys (excludes No Test and TNTC or Non Quantifiable readings)

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Min	0	0	0	0	0	0	0	0	0	0	0	0	0
Max	93	85	73	87	78	80	78	79	70	80	87	67	
Avg	15.78	16.2	16.14	16.45	16.8	16.16	16.28	16.53	16.59	16.3	16.87	15.97	
Count	1349	1278	1424	1289	1227	1434	1350	1283	1373	1341	1353	1007	

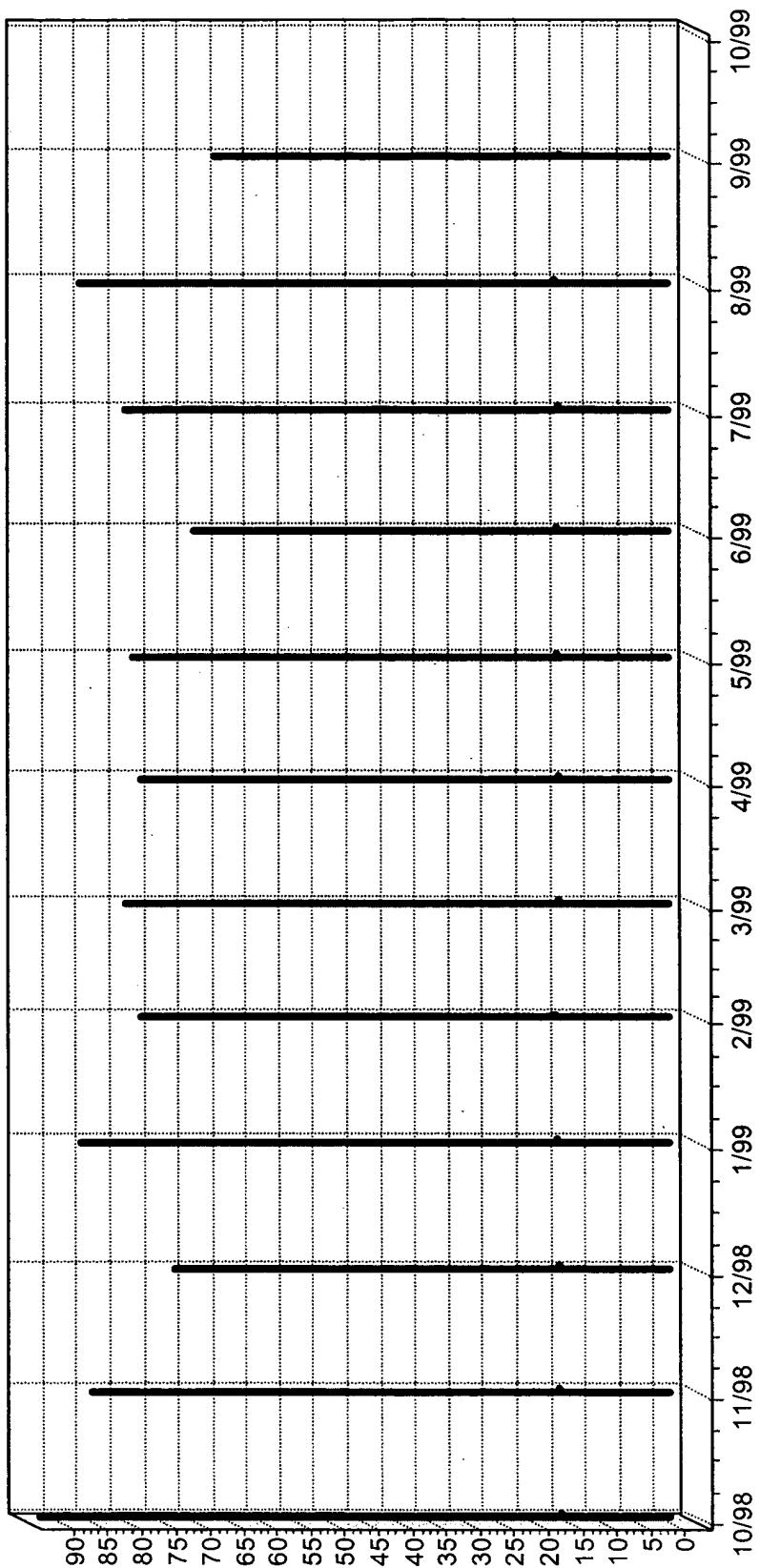
New Test Summary

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
Count	25	32	29	29	30	26	30	27	25	23	18	21	

Alert and Action Limit Excursions

	Oct,98	Nov,98	Dec,98	Jan,99	Feb,99	Mar,99	Apr,99	May,99	Jun,99	Jul,99	Aug,99	Sep,99	Oct,99
>Alert	292	292	339	322	321	347	341	302	336	314	333	232	
>Action	95	110	115	93	96	108	87	109	122	114	104	78	
OK	994	915	1018	905	845	1020	948	911	961	955	951	733	

Rodac TSA Plates for Floors in Not Classified areas. Min Max Values By Month



Environmental Monitoring System

Report Date: 10/20/1999

Facility: EMS Test Facility

Survey Control No.	1501	Survey Date:	7/13/99	Survey Shift:	1	Room Description	Water	Room # 1	Test Date	Read Date	Sample ID	Test ID	Test Site Description	Test By	Read By	Sample ID	Test ID	Test Site Description	Test By	Read Date	Read By	Sample ID	Test ID	Test Site Description	Test By	Read Date	Read By
Room ID:	30	RefNo	Water 1																								
POT-SPV-00	478	Water TOC																									
ROL-SPV-00	262	Water TOC sample taken at city line system port)																									
ROL-SPV-00	267	Water TOC sample taken at 0.2 micrometer absolute filter inlet																									
ROL-SPV-00	268	Water TOC sample taken at 0.2 micrometer absolute filter outlet																									
ROU-SPV-00	259	Water TOC sample taken at RO membrane 3																									
WPL-SPV-00	253	Water TOC sample taken after UV unit 1																									
WPL-SPV-00	255	Water TOC sample taken after RO pre-filter/before overflow line																									
WPL-SPV-00	256	Water TOC sample taken after RO pre-filter/after overflow line (TS)																									
WPL-SPV-01	479	Water TOC sample taken after carbon tank 1																									

Survey Results By Product/Lot

Page: 1 of 1

Date: _____

Reviewed By: _____

CSSC Pharmaceuticals

Environmental Monitoring System

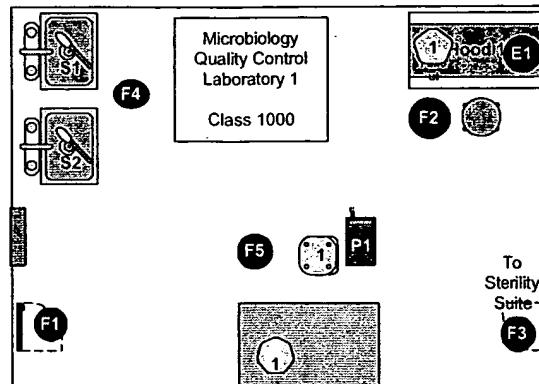
Report Date: 10/20/99

Alert / Action Exceptions From
Sep 01 1999 To Oct 20 1999

Room ID 4 Room Ref I MicroLab1

Room Description

Micro Lab 1



Test ID	Test UserRef	Test Description	Alert Limit	Action Limit	Test Date	Shift	Reading	Condition
15	F3	Floor site in doorway - to sterility suite.	25	30	09-01-1999	1	100	> Action
19	S1	Swab sample within sink 1.	40	50	09-01-1999	1	93	> Action
19	S1	Swab sample within sink 1.	40	50	09-03-1999	1	89	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-06-1999	3	39	> Action
20	S2	Swab sample within sink 2.	40	50	09-06-1999	2	54	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-06-1999	3	5	> Action
14	F2	Floor site in front of laminar flow hood.	25	30	09-07-1999	2	100	> Action
16	F4	Floor site in front of sinks.	35	45	09-07-1999	3	100	> Action
19	S1	Swab sample within sink 1.	40	50	09-07-1999	2	300	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-07-1999	2	300	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-07-1999	3	61	> Action
17	F5	Floor site in center of room.	25	30	09-08-1999	1	58	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-08-1999	3	33	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-09-1999	3	300	> Action
16	F4	Floor site in front of sinks.	35	45	09-10-1999	3	67	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-10-1999	1	300	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-13-1999	2	34	> Action
19	S1	Swab sample within sink 1.	40	50	09-13-1999	2	300	> Action
16	F4	Floor site in front of sinks.	35	45	09-14-1999	2	59	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-14-1999	1	300	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-15-1999	1	53	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-15-1999	3	56	> Action
15	F3	Floor site in doorway - to sterility suite.	25	30	09-15-1999	3	56	> Action
18	E1	Site on work surface of laminar flow hood.	15	20	09-15-1999	3	26	> Action
21	1	Fallout plate within laminar flow hood.	2	3	09-15-1999	2	5	> Action
23	1	Airborne contamination count taken in center of room.	30	40	09-15-1999	1	50	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-16-1999	1	46	> Action
13	F1	Floor site in doorway - room entrance.	25	30	09-16-1999	3	31	> Action
17	F5	Floor site in center of room.	25	30	09-16-1999	1	58	> Action

Environmental Monitoring System

Report Date: 10/20/99

Alert/Action Exceptions From
Sep 01 1999 To Oct 20 1999

23 1	Airborne contamination count taken in center of room.	30	40	09-16-1999	3	300	> Action
13 F1	Floor site in doorway - room entrance.	25	30	09-17-1999	2	51	> Action
21 1	Fallout plate within laminar flow hood.	2	3	09-17-1999	1	4	> Action
23 1	Airborne contamination count taken in center of room.	30	40	09-17-1999	1	44	> Action
23 1	Airborne contamination count taken in center of room.	30	40	09-17-1999	3	78	> Action
18 E1	Site on work surface of laminar flow hood.	15	20	09-20-1999	1	100	> Action
19 S1	Swab sample within sink 1.	40	50	09-20-1999	2	300	> Action
20 S2	Swab sample within sink 2.	40	50	09-20-1999	1	300	> Action
21 1	Fallout plate within laminar flow hood.	2	3	09-21-1999	1	5	> Action
20 S2	Swab sample within sink 2.	40	50	09-22-1999	2	71	> Action

Environmental Monitoring System

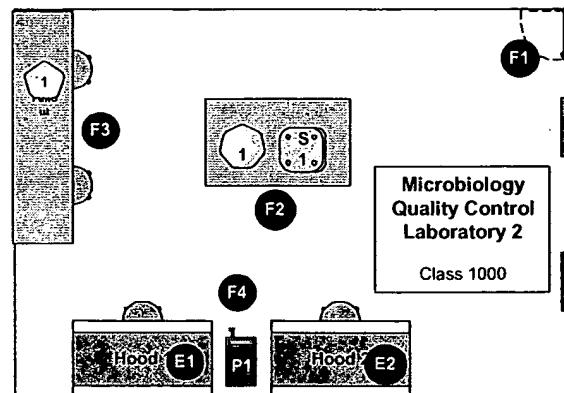
Report Date: 10/20/99

Alert / Action Exceptions From
Sep 01 1999 To Oct 20 1999

Room ID 5 Room Ref I MicroLab2

Room Description

Micro Lab2



Test ID	Test UserRef	Test Description	Alert Limit	Action Limit	Test Date	Shift	Reading	Condition
8	E1	Site on work surface of laminar hood 1.	6	8	09-01-1999	2	100	> Action
8	E1	Site on work surface of laminar hood 1.	6	8	09-01-1999	3	15	> Action
10	RWatson	Personnel touch plate.	4	5	09-01-1999	1	300	> Action
10	TNucci	Personnel touch plate.	4	5	09-01-1999	1	8	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-01-1999	1	60	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-01-1999	3	300	> Action
5	F2	Floor in center of room.	15	20	09-02-1999	1	100	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-02-1999	3	12	> Action
10	SBellman	Personnel touch plate.	4	5	09-02-1999	1	6	> Action
11	S1	Airborne contamination STA plate in center of room.	20	30	09-02-1999	1	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-03-1999	1	100	> Action
4	F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-03-1999	1	100	> Action
5	F2	Floor in center of room.	15	20	09-03-1999	1	27	> Action
8	E1	Site on work surface of laminar hood 1.	6	8	09-03-1999	2	100	> Action
10	TNucci	Personnel touch plate.	4	5	09-03-1999	1	300	> Action
4	F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-06-1999	2	100	> Action
6	F1	Floor in doorway / room entrance	15	20	09-06-1999	3	25	> Action
6	F1	Floor in doorway / room entrance	15	20	09-07-1999	2	24	> Action
7	F5	Floor in room corner - assess general room cleanliness.	20	30	09-07-1999	2	52	> Action
10	SBellman	Personnel touch plate.	4	5	09-07-1999	2	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-09-1999	2	85	> Action
10	RWatson	Personnel touch plate.	4	5	09-09-1999	1	6	> Action
10	TNucci	Personnel touch plate.	4	5	09-09-1999	2	300	> Action
3	F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-10-1999	1	100	> Action
10	JSmith	Personnel touch plate.	4	5	09-10-1999	3	7	> Action
5	F2	Floor in center of room.	15	20	09-13-1999	2	100	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-13-1999	2	16	> Action
9	E2	Site on work surface of laminar hood 2.	6	8	09-13-1999	3	100	> Action

Environmental Monitoring System

Report Date: 10/20/99

Alert / Action Exceptions From Sep 01 1999 To Oct 20 1999

10 TNucci	Personnel touch plate.	4	5	09-13-1999	1	10	> Action
11 S1	Airborne contamination STA plate in center of room.	20	30	09-13-1999	2	300	> Action
4 F4	Floor between hood #1 and hood #2. Sample approx 2 feet in front.	10	15	09-14-1999	2	29	> Action
10 RWatson	Personnel touch plate.	4	5	09-14-1999	2	8	> Action
10 RWatson	Personnel touch plate.	4	5	09-14-1999	3	300	> Action
5 F2	Floor in center of room.	15	20	09-15-1999	3	30	> Action
7 F5	Floor in room corner - assess general room cleanliness.	20	30	09-15-1999	3	44	> Action
3 F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-16-1999	3	100	> Action
12 P1	Particulate count taken between laminar flow hoods.	300	500	09-16-1999	2	669	> Action
8 E1	Site on work surface of laminar hood 1.	6	8	09-17-1999	3	15	> Action
10 SBellman	Personnel touch plate.	4	5	09-17-1999	3	8	> Action
11 S1	Airborne contamination STA plate in center of room.	20	30	09-20-1999	1	300	> Action
12 P1	Particulate count taken between laminar flow hoods.	300	500	09-20-1999	1	856	> Action
3 F3	Floor between workstations approx 2 feet in front of work table.	50	65	09-22-1999	1	100	> Action
7 F5	Floor in room corner - assess general room cleanliness.	20	30	09-22-1999	2	55	> Action
10 SBellman	Personnel touch plate.	4	5	09-22-1999	2	9	> Action

Environmental Monitoring System

Report Date: 10/21/99

Micro Gowning Area

Room/Area:

	1998						1999						Total		
	9	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total
Floor site in doorway - room entrance.	0	0	0	2	0	1	0	0	0	1	0	0	0	0	0
	100	100	100	100	100	75	100	41	100	100	100	100	100	100	100
	20	68	64	73	225	66	62	71	66	62	69	68	51	584	809
Floor site in doorway leading to controlled area.	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	38	100	100	34	100	100	100	38	100	100	100	100	100	100	100
	20	69	65	72	226	66	62	74	68	66	70	67	52	595	821
Floor site on clean site of bench designating class transition area.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	50	100	100	100	100	100	100	46	38	35	100	100	100	100	100
	20	70	67	73	230	65	62	74	67	65	67	70	70	52	592
Floor site on wash side of bench designating class transition area.	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0
	61	100	100	100	100	100	100	44	80	100	100	100	100	100	100
	18	70	66	73	227	66	63	71	68	66	66	67	70	49	590
Particulate count taken in center of clean area.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10	9	10	10	10	9	10	9	10	8	10	8	6	7	10
	19	70	65	72	226	66	64	72	70	66	69	69	70	50	596
	3	3	3	3	3	3	2	3	3	3	3	3	2	2	822
Particulate count taken in center of wash area.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	11	10	8	13	13	11	12	10	11	9	11	13	12	13	13
	20	70	65	73	228	65	62	72	70	67	69	69	68	52	594
RCS airborne contamination sample taken in center of clean area.	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0
	76	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	19	69	64	74	226	66	61	72	70	64	71	69	70	51	594
RCS airborne contamination sample taken in center of wash area.	2	0	0	2	0	1	1	0	0	0	0	0	2	0	0
	300	96	300	93	300	300	300	300	300	300	300	300	300	300	300
	20	69	67	73	229	67	62	73	68	66	71	69	69	50	595
Swab sample within sink 1.	0	0	2	0	0	0	0	0	0	1	4	0	1	2	0
	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	20	69	66	73	228	65	61	74	69	66	71	67	68	51	592
	67	56	41	47	59	52	49	40	63	49	44	46	43	43	824
Swab sample within sink 2.	0	0	1	0	0	0	2	1	0	0	0	2	1	0	0
	93	122	300	300	300	119	300	300	300	300	300	300	300	300	300
	20	69	66	71	226	65	64	73	68	67	69	68	52	595	821
	41	41	47	48	66	41	53	47	57	49	52	51	39	39	821

Environmental Monitoring System

Report Date: 10/21/99

12 Month Historical Data By Room or Area

	1998												1999												Total	
	9	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total											
Wall site near door leading to controlled area.	1	1	0	0	0	0	100	100	100	0	0	100	100	100	100	0	0	0	0	0	0	0	0	0	0	
Wall site near doorway - room entrance.	43	100	100	100	400	64	73	223	66	62	73	68	66	69	67	100	100	100	100	54	100	100	100	100	100	
Wall site near doorway - room entrance.	19	67	64	73	227	21	22	27	22	21	25	22	19	22	20	20	22	22	19	69	69	67	69	51	591	814
Wall site on near wall - general cleanliness assessment.	1	1	0	1	0	0	0	1	2	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
Total	30	28	29	28	115	66	74	226	66	63	74	69	66	69	69	100	100	100	100	100	100	100	100	100	100	
	0	1	0	0	0	2	1	1	1	3	32	25	25	24	25	25	25	27	27	28	28	28	28	28	28	
	51	126	124	124	126	100	114	127	123	108	118	126	121	121	121	121	121	121	121	87	127	127	127	127	127	
	20	70	65	72	227	65	63	74	68	66	69	69	67	67	67	67	67	67	67	49	590	590	590	590	590	
	26	44	40	37	35	36	39	37	38	34	35	34	35	35	35	35	35	35	41	37	37	37	37	37	37	
Total	300	300	300	300	300	946	2,947	854	811	947	889	853	903	893	891	300	300	300	300	300	300	300	300	300	300	
	254	897	850	897	850	254	897	850	811	947	889	853	903	893	891	659	659	659	659	659	659	659	659	659	659	

Environmental Monitoring System

Report Date: 10/21/99

Micro Lab 1

Room/Area:

Micro Lab 1

	1998					1999					Total				
	9	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total
Airborne contamination count taken in center of room.	6	0	0	1	0	0	0	0	0	1	0	0	0	0	0
	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
Fallout plate within laminar flow hood.	18	66	62	68	214	63	59	67	66	62	65	65	64	46	557
	40	23	39	32	32	23	26	27	35	31	34	45	48	48	771
Floor site in center of room.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	5	300	6	300	300	300	300	300	300	300	300	300	300	300	300
Floor site in center of room.	2	15	2	6	215	62	59	68	65	62	65	65	64	48	558
	18	17	19	18	11	7	10	11	6	6	2	7	8	8	773
Floor site in doorway - room entrance.	2	0	0	1	0	0	0	0	0	1	0	1	1	1	0
	55	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Floor site in doorway - to sterility suite.	18	65	63	69	215	63	59	68	64	61	65	64	63	47	551
	17	23	25	20	23	21	22	15	20	21	21	23	18	16	763
Floor site in front of laminar flow hood.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Floor site in front of sinks.	18	63	61	69	211	63	59	67	65	62	66	66	66	46	563
	23	19	22	21	21	17	19	19	18	18	19	17	17	16	775
Particulate count taken in room center.	46	0	1	0	0	0	0	0	0	0	0	0	0	0	0
	3,423	2,318	3,542	3,617	3,472	1,889	3,509	2,700	1,886	3,686	3,591	3,687	1,763	3,689	3,689
Settling plate taken on work surface.	3	0	0	0	0	0	0	0	29	26	29	25	28	22	0
	48	300	300	300	53	300	53	300	300	300	300	300	300	300	300
Site on work surface of laminar flow hood.	2	0	100	100	100	100	100	100	100	100	100	100	100	100	100
	100	66	62	69	215	60	68	65	62	65	66	65	48	561	776
	18	13	12	13	12	13	12	14	16	14	13	10	15	13	776

CSSC Pharmacuticals

Min	Max
Count	Average

Environmental Monitoring System

Report Date: 10/21/99

		1998						1999								
		9	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total
Swab sample within sink 1.	0	0	1	1	0	1	0	1	0	0	0	0	0	0	0	0
	86	300	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	18	64	62	65	209	58	68	65	62	64	64	66	46	46	556	556
	30	33	33	32	41	40	28	32	40	38	47	26	46	46	765	765
Swab sample within sink 2.	2	0	0	0	0	2	0	1	0	2	0	0	3	1	0	0
	300	93	300	87	300	300	300	91	300	77	300	300	300	300	300	300
	18	66	62	66	212	60	69	66	60	63	65	66	47	47	556	556
	56	28	59	28	43	44	43	43	47	29	33	38	34	34	0	0
Total	3,423	2,318	3,542	3,617	3,472	1,889	3,509	2,700	1,886	3,689	3,591	3,687	1,763	1,763	3,689	3,689
	214	779	743	813	2,549	743	708	813	781	743	779	781	562	562	6,688	9,237

Environmental Monitoring System

Report Date: 10/21/99

Room/Area: Micro Lab2

	1998						1999						Total	
	9	10	11	12	Total	1	2	3	4	5	6	7	8	
Airborne contamination STA plate in center of room.	2	0	0	0	0	0	0	0	0	0	0	0	0	0
	49	300	52	300	300	41	300	58	300	300	300	300	300	300
	18	65	63	69	215	60	58	65	63	65	66	48	558	773
Floor between hood #1 and hood #2. Sample approx 2 feet in front of table.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	15	100	100	100	100	100	24	100	100	100	100	25	100	100
	17	65	61	69	212	61	59	67	66	60	64	66	48	556
Floor Between workstations approx 2 feet in front of work table.	1	1	1	0	0	0	0	0	0	3	0	1	0	6
	108	100	114	123	111	100	101	122	130	127	122	114	100	130
	18	64	62	69	213	62	59	69	66	63	64	66	47	560
Floor in center of room.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	10	100	100	100	100	100	100	100	100	100	100	100	100	100
	18	65	63	68	214	62	60	65	63	63	64	64	48	558
Floor in doorway / room entrance	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	30	12	18	14	13	17	19	14	14	14	12	14	14	772
Floor in room corner - assess general room cleanliness.	1	0	0	0	0	0	0	0	0	0	0	0	0	0
	40	100	60	100	100	100	100	100	100	100	100	100	100	100
	18	66	62	67	213	63	58	68	65	63	66	66	46	556
Particulate count taken between laminar flow hoods.	0	5	0	0	0	0	0	0	0	0	0	1	1	0
	13	20	15	19	21	20	16	18	19	17	16	19	17	772
Personnel touch plate.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	487	945	683	733	945	743	950	873	720	986	842	950	930	856
	17	65	62	68	212	62	60	67	64	63	65	63	47	556
	257	267	288	279	247	271	272	223	290	232	330	282	225	986
	300	300	300	300	300	300	300	300	300	300	300	300	300	300
	72	256	248	270	846	250	234	273	259	244	260	257	260	185
	11	13	12	11	12	8	9	14	16	13	16	11	11	768
Site on work surface of laminar hood 1.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	16	100	15	100	100	100	11	100	16	100	100	100	100	100
	18	66	60	68	212	60	59	68	64	62	64	65	48	556
	6	8	4	6	9	5	6	4	9	9	7	7	9	3,068
Site on work surface of laminar hood 2.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	13	100	100	100	100	100	100	100	100	100	100	100	100	100
	16	65	61	68	210	63	58	66	61	66	65	65	47	556
	4	9	6	12	13	6	8	6	6	8	9	8	6	766

Environmental Monitoring System

Report Date: 10/21/99

12 Month Historical Data By Room or Area

	1998						1999						Total	
	9	10	11	12	Total	1	2	3	4	5	6	7	8	
Total	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	487	945	683	733	945	743	950	873	720	986	842	950	930	986
	229	843	804	884	2,760	805	762	880	843	805	842	840	848	848

CSSC Pharmaceuticals

Min
Max
Count
Average

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

Rodac TSA Plate

12 Month Summary By Test Type

Micro Gowning Area	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Floor site in doorway - room entrance.	0	0	2	0	0	1	0	0	1	0	0	0	0	0
	100	100	100	100	100	75	100	41	100	100	100	100	100	100
	25.00	29.00	26.00	21.00	21.00	22.00	20.00	27.00	25.00	24.00	26.00	26.00	26.00	26.00
	68	64	73	205	66	62	71	66	62	69	69	68	51	584
Floor site in doorway leading to controlled area.	0	0	0	0	0	0	0	0	0	0	0	1	0	789
	100	100	34	100	100	100	100	38	100	100	100	100	100	100
	13.00	13.00	10.00	14.00	15.00	12.00	11.00	14.00	17.00	16.00	14.00	18.00	18.00	18.00
	69	65	72	206	66	62	74	68	66	70	70	67	52	595
Floor site on clean site of bench designating clas	0	0	0	0	0	0	0	0	0	0	0	0	0	801
	100	100	100	100	100	46	38	35	100	100	100	100	100	100
	14.00	18.00	17.00	15.00	15.00	14.00	14.00	20.00	20.00	17.00	16.00	17.00	15.00	15.00
	70	67	73	210	65	62	74	67	65	67	70	70	52	592
Floor site on wash side of bench designating clas	0	0	0	0	1	0	1	0	0	0	0	0	0	302
	100	100	100	100	100	44	80	100	100	100	100	100	100	100
	22.00	25.00	20.00	20.00	20.00	19.00	24.00	24.00	30.00	23.00	25.00	23.00	29.00	29.00
	66	73	209	66	63	63	71	68	66	70	67	70	49	590
Wall site near door leading to controlled area.	1	0	0	0	0	0	0	0	0	0	0	0	0	799
	100	100	100	100	100	100	100	100	100	100	100	100	100	100
	21.00	22.00	27.00	22.00	22.00	21.00	25.00	22.00	19.00	22.00	20.00	22.00	19.00	19.00
	67	64	73	204	66	62	73	68	66	69	69	67	51	591
Wall site near doorway - room entrance.	1	0	1	0	0	1	2	0	0	0	0	0	0	0
	100	100	100	100	83	100	100	100	100	100	100	100	100	100
	28.00	29.00	28.00	23.00	25.00	34.00	32.00	25.00	24.00	25.00	24.00	25.00	28.00	28.00
	67	66	74	207	66	63	74	69	66	69	69	67	49	592
Wall site on near wall - general cleanliness ass	1	0	0	2	1	1	1	1	3	0	0	2	0	0
	126	124	124	100	114	127	123	108	118	126	121	87	127	127
	44.00	40.00	37.00	35.00	36.00	39.00	37.00	38.00	34.00	35.00	41.00	37.00	37.00	37.00
	70	65	72	207	65	63	74	68	66	69	69	67	49	590
Total	0	0	0	0	0	0	0	0	0	0	0	0	0	797
	126	124	124	126	100	114	127	123	108	118	126	121	100	127
	481	457	510	1,448	460	437	511	474	457	483	481	478	353	4,134
														5,582

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998										1999										Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total								
Micro Lab 1	Floor site in center of room.	0	0	0	0	0	0	1	0	1	0	1	1	1	0	0	0	0	0	0	0	
		100	100	100	100	100	100	100	100	100	100	100	100	100	58	100	100	100	100	100	100	
		17.00	19.00	18.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	19.00	16.00	16.00	16.00	16.00	16.00	16.00	16.00	
		64	64	61	69	194	60	60	67	64	61	65	64	63	47	551	551	551	551	551	551	545
	Floor site in doorway - room entrance.	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	100	100	100	100	100	100	100	100	100	100	100	100	56	100	100	100	100	100	100	
		23.00	25.00	20.00	25.00	20.00	20.00	23.00	21.00	22.00	21.00	19.00	17.00	18.00	23.00	20.00	20.00	20.00	20.00	20.00	20.00	
		65	63	69	63	197	63	59	68	64	62	66	62	65	45	554	554	554	554	554	554	551
	Floor site in doorway to sterility suite.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	100	100	21.00	21.00	19.00	17.00	19.00	19.00	19.00	18.00	18.00	19.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00	
		19.00	21.00	21.00	61	69	195	62	59	69	66	63	66	66	66	46	563	563	563	563	563	563
	Floor site in front of laminar flow hood.	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	100	100	21.00	21.00	16.00	41	100	100	100	100	100	100	100	100	100	100	100	100	100	
		19.00	22.00	22.00	61	69	193	63	59	67	65	62	66	66	66	46	563	563	563	563	563	563
	Floor site in front of sinks.	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		85	85	100	23.00	32.00	26.00	26.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00	
		26.00	24.00	24.00	60	68	194	62	58	68	65	62	66	66	66	47	559	559	559	559	559	553
	Site on work surface of laminar flow hood.	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	100	100	13.00	13.00	12.00	12.00	14.00	16.00	14.00	16.00	14.00	16.00	13.00	13.00	13.00	13.00	13.00	13.00	13.00	
		13.00	12.00	12.00	62	69	197	62	60	68	65	62	65	66	66	48	561	561	561	561	561	558
	Total	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	100	100	356	372	355	407	389	372	394	372	394	389	389	280	280	280	280	280	280	280
		389	368	413	1,170	1,170	1,170	1,170	1,170	1,170	1,170	1,170	1,170	1,170	4,518	4,518	4,518	4,518	4,518	4,518	4,518	
Micro Lab2	Floor between hood #1 and hood #2. Sample approx :	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	11.00	13.00	61	69	195	61	59	67	66	60	64	64	8.00	8.00	8.00	8.00	8.00	8.00	8.00	
		10.00	11.00	11.00	61	69	195	61	59	67	66	60	64	64	66	66	66	66	66	66	66	
	Floor between workstations approx 2 feet in front of work tab	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
		100	114	123	41.00	41.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	40.00	35.00	35.00	35.00	35.00	35.00	35.00	35.00	
		36.00	40.00	40.00	64	62	69	195	62	59	69	66	63	64	64	47	560	560	560	560	560	555

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Micro Lab2	Floor in center of room.	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	14.00	13.00	17.00	19.00	14.00	14.00	100	100	100	100	100
	12.00	18.00	14.00	63	68	62	60	66	65	63	64	66	64	64
	65	63	68											
	Floor in doorway / room entrance	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	13.00	15.00	12.00	13.00	15.00	15.00	100	40	100	25	100
	15.00	13.00	13.00	62	68	62	62	57	64	63	64	66	66	64
	66	62	68											
	Floor in room corner - assess general room cleanliness.	0	0	0	0	0	1	0	0	0	0	1	0	0
	60	100	100	21.00	100	100	100	100	100	100	52	48	55	100
	20.00	15.00	19.00	62	67	195	63	58	68	65	63	66	65	65
	66	62	67											
	Site on work surface of laminar hood 1.	0	0	0	0	0	0	0	0	0	0	0	0	0
	15	100	100	9.00	100	100	100	100	100	100	100	100	100	100
	8.00	4.00	6.00	62	68	194	60	59	68	64	62	64	66	65
	66	60	68											
	Site on work surface of laminar hood 2.	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	13.00	100	100	100	100	100	100	100	100	100	100
	9.00	6.00	12.00	61	68	194	63	58	66	65	61	66	65	65
	66	61	68											
	Total	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	114	123	1,365	334	433	410	472	455	435	127	122	114	130
	457	431	477											
	Micro Sterility Suite	Floor site in doorway - room entrance.	0	0	0	0	0	0	0	0	0	1	0	0
	59	100	100	21.00	22.00	17.00	17.00	16.00	20.00	100	57	100	100	100
	16.00	18.00	21.00	60	68	192	62	57	68	66	62	66	64	65
	64	60	68											
	Floor site in front of laminar flow hood.	1	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	14.00	16.00	14.00	16.00	16.00	21.00	100	46	100	100	100
	16.00	16.00	22.00	60	69	193	60	59	69	66	62	66	65	65
	64	60	69											
	Floor site in room corner - general cleanliness ass	0	0	0	0	0	0	0	1	0	0	0	0	0
	100	100	100	18.00	20.00	18.00	14.00	20.00	17.00	100	57	100	100	100
	18.00	18.00	20.00	63	66	193	62	59	69	65	63	64	66	64
	64	63	66											

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

Micro Sterility Suite	1998												1999												Total				
	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Site on work surface of laminar flow hood.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0			
Total	100	100	100	15.00	13.00	14.00	10.00	15.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00			
Floor site near doorway to room 101.	258	243	269	770	246	233	274	262	249	261	261	260	260	260	260	260	260	260	260	260	260	260	260	260	260	260	260		
Floor site near doorway to room 102.	16	27	2	2	4	2	10	9	2	1	1	16	21	11	28	4	1	1	1	1	1	1	1	1	1	1	1	1	
Floor site near doorway to room 103.	100	39	38	26	31	11	40	38	28	33	38	33	38	33	38	33	38	33	38	33	38	33	38	33	38	33	38	33	
Floor site near doorway to room 104.	12	2	1	1	0	3	12	4	7	14	6	23	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Wall site near doorway to room 101.	37	40	39	23.00	20.00	10.00	47	67	33	100	19	37	21	38	37	100	37	100	37	100	37	100	37	100	37	100	37	100	
Wall site near doorway to room 102.	20.00	17.00	8.00	5	13	4	4	4	5	4	4	14.00	25.00	11.00	30.00	25.00	11.00	30.00	25.00	11.00	30.00	25.00	11.00	30.00	25.00	11.00	30.00	25.00	
Wall site near doorway to room 103.	44.00	44.00	11.00	4	3	4	11	4	4	4	4	34.00	21.00	19.00	21.00	34.00	21.00	19.00	21.00	34.00	21.00	19.00	21.00	34.00	21.00	19.00	21.00	34.00	21.00
Wall site near doorway to room 104.	37	56	29	2	0	5	11	11	2	12	7	23	13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Total	100	100	100	15.00	13.00	14.00	10.00	15.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	13.00	16.00	

Environmental Monitoring System

EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 100 Hallway	2	0	6	0	22	0	2	6	5	3	13	20	0	0
	72	33	41	72	100	32	42	80	43	33	42	44	100	100
Total	30.00	17.00	24.00	5	12	4	4	14.00	28.00	19.00	15.00	16.00	32.00	33.00
	3	4						5	3	4	5	4	4	49
Production Room 101 Gowning Area	2	0	1	0	0	0	2	1	1	1	5	0	0	0
	100	100	100	100	90	44	100	100	70	100	100	62	100	100
Floor site in doorway - room entrance.	31	31	39	101	31	30	39	31	31	40	31	31	30	294
	22.00	22.00	21.00	61	68	193	59	60	21.00	21.00	23.00	24.00	19.00	1,877
Floor site in wash area near bench	0	0	0	0	0	0	0	0	0	0	0	2	0	0
	50	100	100	19.00	62	60	100	100	100	100	100	100	100	100
Floor site near door leading to controlled area.	65	63	67	195	62	60	68	65	62	66	63	65	48	558
	16.00	19.00	19.00	64	61	68	19.00	19.00	20.00	18.00	19.00	18.00	19.00	751
Floor site near door leading to controlled area.	0	1	0	0	0	0	0	0	0	1	0	0	0	0
	100	100	100	20.00	197	61	49	100	37	100	44	100	100	100
Floor site on clean side near bench	65	63	69	197	61	56	69	63	61	62	65	66	45	558
	14.00	17.00	20.00	66	69	16.00	16.00	13.00	13.00	15.00	19.00	14.00	16.00	753
Rodac sample on bench	0	0	0	0	0	1	0	0	0	0	1	0	0	0
	100	100	100	20.00	192	63	59	58	66	63	65	64	66	747
Wall site near doorway - room entrance.	1	0	0	0	0	0	0	0	0	0	1	0	0	0
	100	100	100	60	67	193	63	57	68	65	62	64	47	561
Wall site near doorway - room entrance.	1	2	0	0	0	0	0	0	1	0	0	0	0	0
	100	100	100	62	66	192	62	59	68	64	62	60	64	741

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 101 Gowning Area	Wall site near sink in wash area.	0	0	0	0	0	0	0	0	0	1	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
Production Room 102 Bottle Storage	Floor site in center of room.	3	12	0	0	7	7	4	1	17	2	0	0	0
	33	100	25	100	35	61	38	29	37	30	36	43	41	61
Floor site in corner of room.	Floor site in corner of room.	4	3	2	2	7	10	12	5	18	14	0	0	0
	37	33	100	100	29	38	33	17	32	40	28	100	100	100
Floor site in doorway - room entrance.	Floor site in doorway - room entrance.	13	7	0	0	6	3	2	28	11	4	7	2	0
	51	34	37	51	37	50	36	100	36	100	38	75	39	100
Wall site near doorway - room entrance.	Wall site near doorway - room entrance.	25	100	63	100	22	40	19	35	23	37	16	25	40
	16.00	34.00	32.00	4	5	13	4	4	5	3	4	5	4	100
Wall site on near wall above stored bottles.	Wall site on near wall above stored bottles.	7	2	8	2	11	5	14	4	7	1	10	11	0
	39	33	100	100	66	12	100	46	34	66	36	22	19	100
Total	51	100	0	0	1	3	2	1	3	1	0	4	0	0
	18	20	25	63	19	20	25	19	20	25	20	20	18	249
Production Room 103 Bottling	Floor site in center of room.	7	6	8	6	7	19	0	2	5	8	5	11	0
	16	100	100	31.00	100	38.00	35	18	30	21	34	27	100	100
	13.00	39.00	4	5	13	4	4	5	4	5	4	3	36	49

Environmental Monitoring System
EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 103 Bottling	2	15	4	2	14	3	0	18	13	2	18	0	0	0
Floor site in doorway - room entrance.	18	43	100	100	26	33	41	100	32	100	26	100	100	100
	9.00	27.00	33.00	33.00	18.00	19.00	20.00	34.00	41.00	23.00	47.00	21.00	31.00	49
Floor site near work surface.	4	4	5	13	4	3	5	4	4	4	4	4	4	36
	15.00	20.00	20.00	20.00	9.00	18.00	22.00	17.00	25.00	17.00	12.00	13.00	23.00	50
Floor site within laminar flow curtains near bottling equipment	7	12	1	1	13	7	0	5	6	1	3	10	0	0
	21	33	25	33	31	20	27	25	49	20	13	32	61	61
	16.00	21.00	18.00	18.00	15.00	13.00	16.00	19.00	18.00	8.00	9.00	7.00	7.00	49
Rodac sample on bottling equipment within laminar flow	0	8	1	0	2	4	0	1	7	0	0	0	0	0
	13	17	100	100	23	100	11	11	100	14	12	14	8	100
	5.00	13.00	24.00	24.00	10.00	32.00	7.00	6.00	34.00	8.00	6.00	12.00	4.00	50
Rodac sample on door handle.	0	12	0	18	0	2	8	5	5	3	6	6	0	0
	51	100	100	35	32	23	34	23	100	33	64	34	100	100
	40.00	17.00	53.00	53.00	26.00	12.00	20.00	14.00	34.00	16.00	31.00	18.00	18.00	50
Wall site above countertop.	7	15	3	0	28	9	0	10	1	2	12	10	0	0
	39	100	100	25	35	39	3	35	37	32	75	40	75	100
	36.00	32.00	23.00	23.00	14.00	33.00	29.00	1.00	20.00	11.00	10.00	36.00	32.00	50
Wall site near laminar flow curtains.	6	2	1	5	4	31	37	61	31	3	6	7	18	1
	35	40	40	34	40	15.00	22.00	27.00	22.00	17.00	28.00	40	100	100
	15.00	15.00	19.00	19.00	13.00	35.00	45.00	10.00	39.00	43.00	14.00	45.00	4	49
Wall site on far wall near air return grate.	11	9	4	15	26	0	1	11	0	7	1	0	0	0
	100	100	100	31	68	100	28	100	100	29	35	28	100	100
	35.00	25.00	53.00	53.00	12	4	5	4	4	4	4	4	4	49
Total	0	1	0	0	0	0	0	1	0	0	1	0	0	0
	100	100	100	100	100	100	100	100	100	100	75	100	100	100
	34	35	44	113	35	35	45	35	36	43	34	35	35	446

Environmental Monitoring System

12 Month Summary By Test Type

Facility: EMS Test Facility

Report Date: 10/21/99

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 104 Capping	29	22	5	5	2	4	7	1	17	0	4	6	12	0
Floor site between workstations near countertop.	16.00	14.00	16.00	5	13	4	24	26	24	26	59	26	100	100
Floor site in doorway - room entrance.	15	2	10	2	12	5	8	3	5	0	0	12	1	0
Floor site in room corner - general cleanliness ass	100	25	100	20.00	20.00	23.00	19.00	16.00	15.00	18	58	19.00	27	0
Floor site in room corner - general cleanliness ass	18.00	17.00	43.00	5	13	4	4	5	4	5	4	19.00	14.00	51
Floor site within laminar flow curtains near capper.	1	3	0	0	5	3	11	2	4	13	14	3	6	2
Rodac site on capping equipment within laminar fl	40	29	31	40	37	27	25	62	34	38	100	9	30	0
Rodac site on production surface.	17.00	18.00	17.00	17.00	19.00	17.00	17.00	30.00	17.00	29.00	39.00	7.00	21.00	100
Wall site on window near laminar flow curtains.	25	24	0	0	12	10	10	18	39	16	15	40	19	0
Total	100	100	31	100	100	37	100	100	100	38	100	40	100	100
Production Room 205 Raw Material Storage	39	29	39	39	354	102	32	31	40	32	31	40	31	31

Environmental Monitoring System

12 Month Summary By Test Type

Facility: EMS Test Facility

Report Date: 10/21/99

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 205 Raw Material Storage	5	2	5	2	1	2	26	17	5	16	3	8	4	1
Floor site near desk in corner of room.	23	25	32	32	36	42	34	100	36	29	25	35	100	100
	14.00	14.00	23.00	12	16.00	23.00	32.00	25.00	38.00	25.00	14.00	21.00	44.00	37
Floor site near doorway - room entrance.	14	3	5	5	12	4	3	5	4	5	4	4	4	49
Wall site near doorway - room entrance.	13	8	12	8	19	0	0	6	8	6	5	11	8	0
	35	39	40	40	40	15	64	32	40	28	39	40	100	100
	18.00	24.00	24.00	12	33.00	6.00	22.00	21.00	22.00	18.00	19.00	25.00	44.00	37
Wall site near stored raw materials.	26	13	31	13	5	5	5	26	1	6	20	33	0	0
	47	82	100	100	42	32	39	46	31	39	47	49	34	0
	43.00	47.00	51	13	17.00	22.00	21.00	34.00	19.00	27.00	32.00	39.00	13.00	49
	4	4	5	13	4	4	4	5	4	4	5	4	3	49
Total	1	2	0	0	1	0	0	2	1	6	2	8	0	51
	47	82	100	100	42	70	64	100	100	39	75	100	100	2
	20	19	24	63	20	19	25	20	20	25	20	20	19	100
Production Room 206 Personnel Prep Area	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Floor site near doorway - room entrance.	100	100	48	100	48	100	100	45	100	100	100	100	100	100
	16.00	16.00	17.00	72	204	66	63	70	68	65	71	69	70	251
Floor site near lockers and bench.	0	0	0	0	2	0	1	0	0	0	0	0	0	0
	100	100	25.00	72	208	67	63	71	69	66	70	70	52	58
Floor site near sinks 1 and 2.	3	8	9	3	0	16	0	0	5	7	12	19	6	0
	22	21	36	36	33	34	34	36	52	58	37	32	38	58
	14.00	15.00	25.00	5	13	4	4	5	3	4	5	4	4	50
Floor site near sinks 2 and 3.	2	4	0	0	19	0	0	3	10	6	17	10	4	0
	100	40	26	100	69	100	24	21	35	100	54	100	18	100
	30.00	25.00	14.00	5	13	37.00	35.00	10.00	23.00	32.00	5	4	4	51

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998												1999												Total			
	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	10	11	12	Total	1	2	3	4	5	6	7	8	9	Total
Production Room 206 Personnel Prep Area	Wall site near doorway - room entrance.	15 44 29.00	3 24 10.00	12 99 40.00	3 99 5	3 37 22.00	5 14 10.00	5 40 20.00	5 41.00	22 73 17.00	10 28 43.00	19 100 31.00	10 42 31.00	10 42 19.00	13 41 21.00	5 41 4	3 42 4	3 42 4	13 41 21.00	10 42 31.00	10 42 19.00	13 41 21.00	5 41 4	3 42 4	11 42 22.00	0 68 22.00	0 68 22.00	5 79 37
Wall site near lockers.	3 38 20.00	6 46 28.00	3 79 37.00	3 79 31.00	11 48 32.00	24 42.00	50 48.00	58 48.00	31 29.00	31 15.00	31 38 34.00	31 46 34.00	29 38 34.00	50														
Wall site near sink 3.	0 99 29.00	2 52 27.00	1 100 29.00	1 100 31.00	0 100 25.00	0 100 31.00	0 100 31.00	0 100 31.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00	0 100 33.00
Total	0 100 220	0 100 214	0 100 237	1 100 671	1 100 207	0 100 73	0 100 65	0 100 64	0 100 74	0 100 69	0 100 67	0 100 70	0 100 68	0 100 67	801													
Production Room 207 Tablet Milling	Floor site in center of room.	1 34 18.00	2 33 17.00	5 30 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	1 34 22.00	50							
Floor site near doorway - room entrance.	14 65 33.00	12 17 14.00	5 34 20.00	5 65 20.00	0 32 23.00	3 30 15.00	3 30 15.00	3 30 15.00	3 30 15.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	0 35 30.00	65
Floor site near work surface.	4 43 25.00	20 34 29.00	11 100 40.00	4 100 40.00	1 100 10.00	8 40 26.00	1 40 26.00	1 40 26.00	1 40 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	0 31 26.00	51	
Floor site within laminar flow curtains near tablet miller.	0 21 11.00	0 14.00 4	0 14.00 4	0 14.00 4	0 14.00 5	0 14.00 5	0 14.00 5	0 14.00 5	0 14.00 5	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	1 11.00 4	48		
Wall site near doorway - room entrance.	19 31 26.00	2 22 14.00	4 48 21.00	2 48 21.00	1 43 8.00	1 43 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	0 20 8.00	51

Environmental Monitoring System
EMS Test Facility
 Report Date: 10/21/99

12 Month Summary By Test Type

		1998						1999						Total		
		10	11	12	Total	1	2	3	4	5	6	7	8	9	Total	
Production Room 207	Total	0	0	0	0	0	0	0	2	0	0	3	1	0	0	
Tablet Milling		65	34	100	100	43	57	65	58	100	100	35	34	33	100	
Production Room 208		20	19	25	64	20	19	24	20	19	20	20	19	185	249	
Tablet Milling																
Floor site in center of room.		7	38	4	10	12	4	17	2	15	2	6	5	2	2	
		29	100	25	100	35	39	34	100	26	36	23	40	38	100	
Production Room 208		18.00	55.00	9.00	25.00	23.00	17.00	43.00	16.00	25.00	11.00	22.00	17.00	4	38	51
Packaging																
Floor site near boxing equipment.		11	1	3	1	3	9	11	13	4	0	3	5	1	0	
		63	24	29	63	31	100	33	33	53	34	55	40	24	100	
Production Room 208		30.00	11.00	14.00	16.00	45.00	20.00	20.00	26.00	15.00	33.00	21.00	11.00	11.00	100	
Packaging																
Floor site near doorway - room entrance.		26	1	2	1	15	4	4	13	3	5	2	11	7	2	
		80	16	36	80	38	36	50	37	26	65	19	61	34	65	
Production Room 208		52.00	9.00	21.00	13	4	4	4	5	4	3	5	4	4	37	50
Packaging																
Floor site near sink.		8	18	6	6	21	1	1	8	15	16	6	13	0	0	
		34	100	54	100	34	41	100	37	44	31	31	35	35	100	
Production Room 208		19.00	42.00	19.00	5	13	4	4	5	4	4	4	4	4	36	49
Packaging																
Rodac site on boxing equipment.		2	8	8	2	13	1	12	10	4	2	8	19	14	1	
		31	37	33	37	80	100	32	54	59	29	37	100	48	100	
Production Room 208		10.00	20.00	24.00	5	13	4	4	5	4	3	5	43.00	27.00	50	
Packaging																
Wall site near doorway - room entrance.		7	1	0	0	2	7	2	13	4	9	8	0	6	0	
		41	100	32	100	25	47	33	73	58	90	34	100	56	100	
Production Room 208		23.00	35.00	13.00	5	13	4	4	5	4	4	5	4	4	37	50
Packaging																
Wall site near doorway - room entrance.		0	16	0	0	16	11	15	14	1	29	3	13	1	0	
		100	34	42	100	30	35	43	65	21	53	78	38	34	78	
Production Room 208		38.00	25.00	19.00	5	13	4	4	5	4	4	5	4	4	37	50
Packaging																
Total		0	1	0	0	2	1	1	8	1	0	2	0	0	0	
		100	100	54	100	80	100	100	100	59	90	78	100	56	100	
		28	28	35	91	28	27	35	28	26	34	27	27	28	260	
															351	

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

12 Month Summary By Test Type

	1998						1999						Total	
	10	11	12	Total	1	2	3	4	5	6	7	8	9	
Production Room 209 Lyophilization	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Equipment site on the door of lyophilizer 1.	100	100	100	300	15	100	100	100	100	100	26	100	100	100
	9.00	10.00	13.00		8.00	13.00	11.00	12.00	9.00	11.00	7.00	12.00	10.00	100
	69	67	73	209	67	63	71	68	67	70	68	69	52	595
Equipment site on the door of lyophilizer 2.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	10.00	10.00	15.00		10.00	14.00	10.00	12.00	10.00	12.00	11.00	12.00	12.00	100
	65	65	73	206	67	64	74	68	67	70	69	68	51	598
Equipment site on the door of lyophilizer 3.	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	15.00	15.00	11.00		12.00	11.00	11.00	12.00	10.00	12.00	14.00	12.00	12.00	100
	68	68	73	208	65	61	71	68	64	71	69	68	51	584
Floor site in center of room.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	17.00	17.00	17.00		18.00	18.00	18.00	18.00	17.00	17.00	16.00	16.00	16.00	100
	69	69	73	207	66	63	71	67	67	70	69	68	70	786
Floor site near work surface.	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	16.00	16.00	16.00		18.00	18.00	18.00	18.00	17.00	17.00	16.00	16.00	16.00	100
	69	69	73	208	67	63	74	63	67	71	70	69	52	596
Floor site within laminar flow curtains between lyophilii	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	13.00	13.00	15.00		11.00	12.00	12.00	13.00	13.00	14.00	16.00	16.00	16.00	100
	69	69	70	205	64	63	72	69	66	70	67	71	51	599
Floor site within laminar flow curtains between lyophilii	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	12.00	12.00	14.00		12.00	12.00	12.00	12.00	12.00	12.00	13.00	13.00	13.00	100
	70	66	71	207	66	63	73	63	67	71	70	67	52	593
Wall site above work surface.	0	0	0	0	0	0	0	0	0	0	1	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	21.00	22.00	22.00		16.00	15.00	20.00	22.00	21.00	21.00	21.00	23.00	24.00	100
	69	65	74	208	63	63	70	69	66	69	68	68	51	587
Wall site near doorway - room entrance.	0	0	0	0	0	0	0	1	0	1	0	0	0	0
	100	100	100	300	100	100	100	100	100	100	100	100	100	100
	25.00	25.00	17.00		21.00	23.00	18.00	23.00	17.00	19.00	17.00	18.00	20.00	100
	67	67	71	205	65	63	72	70	65	71	69	67	51	593

Environmental Monitoring System

Facility: EMS Test Facility

Report Date: 10/21/99

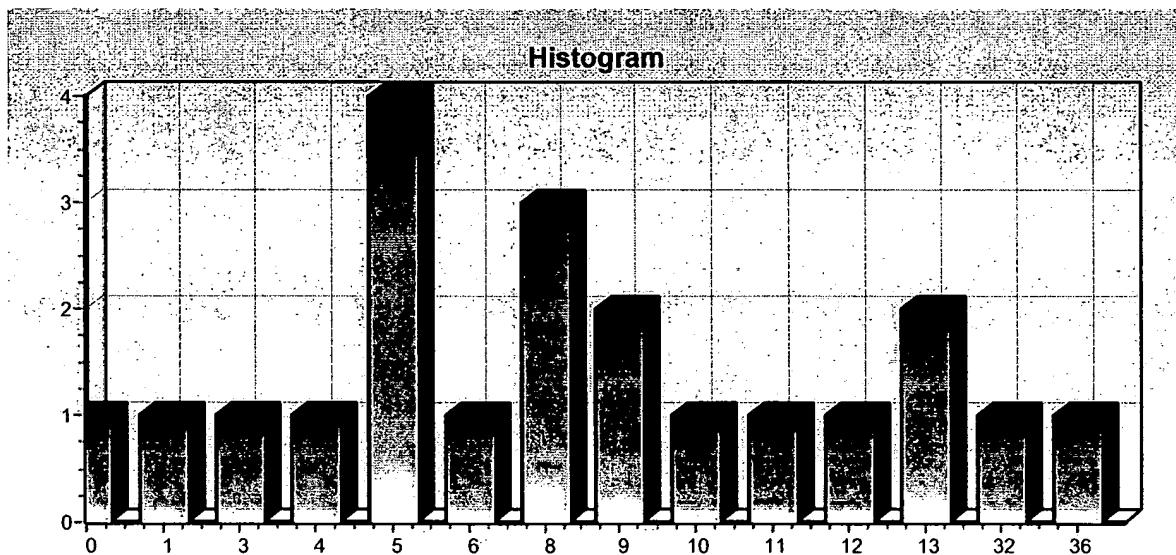
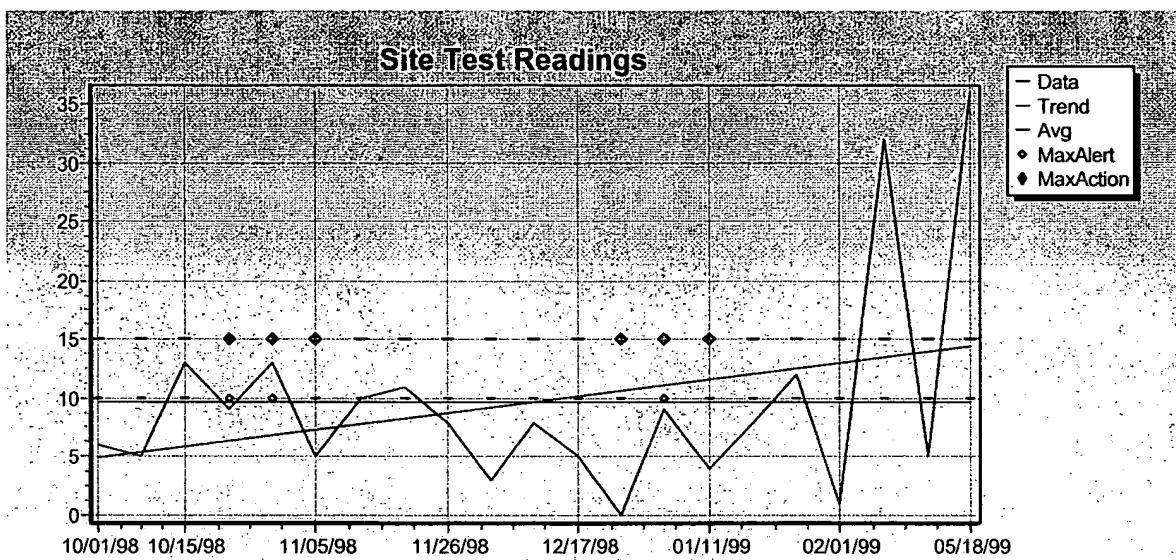
12 Month Summary By Test Type

	Total	1998						1999						Total
		10	11	12	Total	1	2	3	4	5	6	7	8	
Production Room 209	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lyophilization	100	100	100	100	100	100	100	100	100	100	100	100	100	100
Total	619	592	652	1,863	590	566	648	616	593	632	618	618	462	5,343
														7,206

Environmental Monitoring
System
Report Date: 10/20/99

Test Site Charts
From: Oct 01 1998 To: Oct 20 1999

Room: Production Room 209 Lyophilization
Test Site: Equipment site on the door of lyophilizer 1.



Environmental Monitoring System

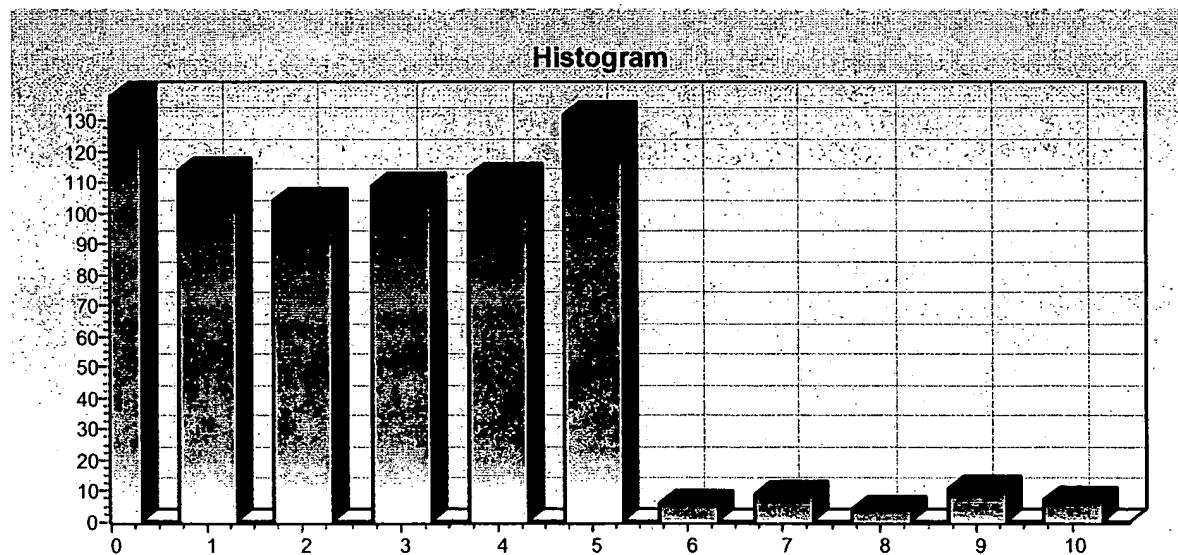
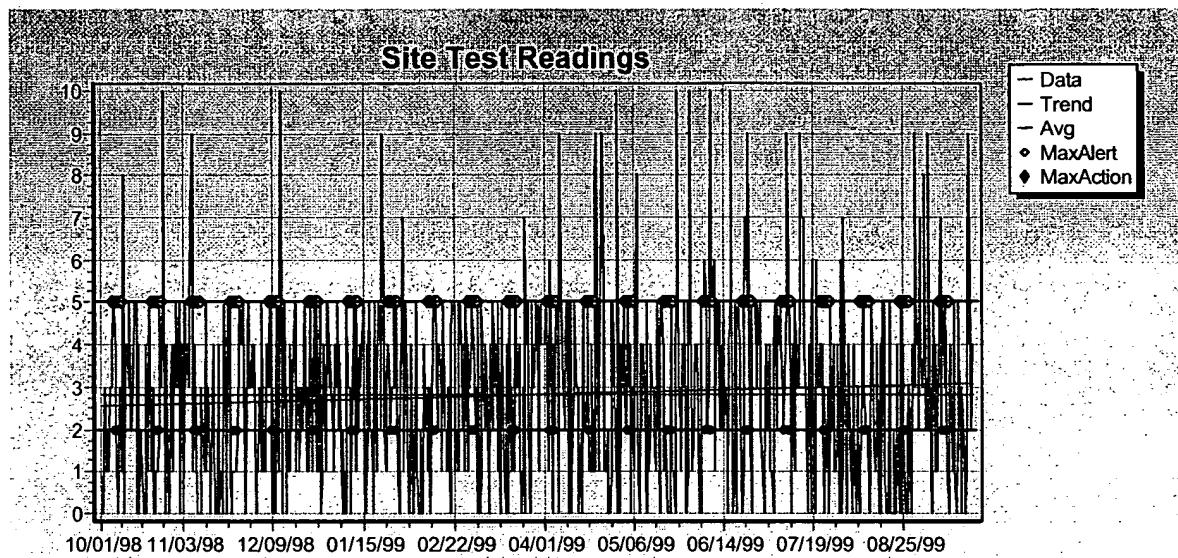
Report Date: 10/21/99

Test Site Charts

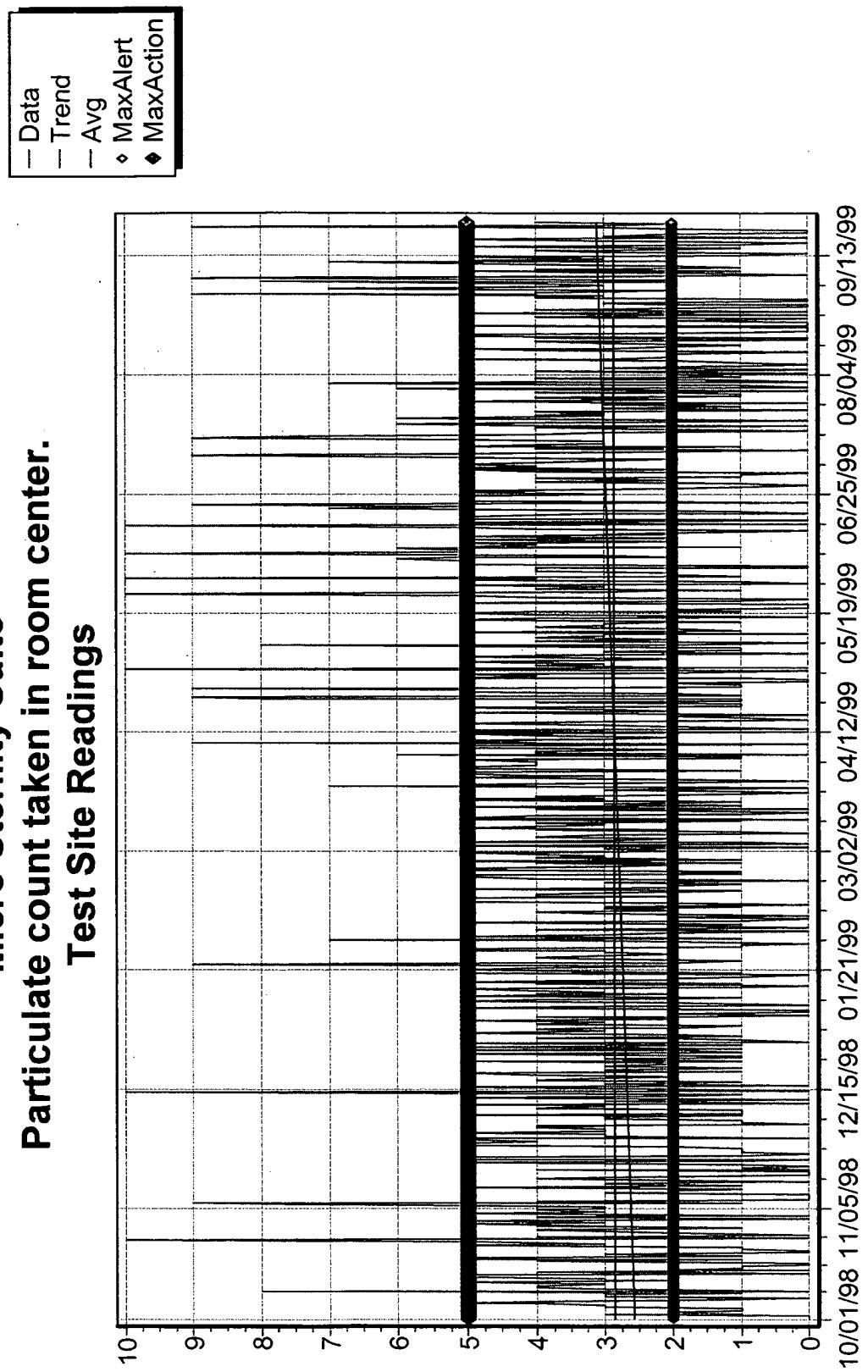
From: Oct 01 1998 To: Oct 21 1999

Room: Micro Sterility Suite

Test Site: Particulate count taken in room center.



Micro Sterility Suite
Particulate count taken in room center.
Test Site Readings



Environmental Monitoring System

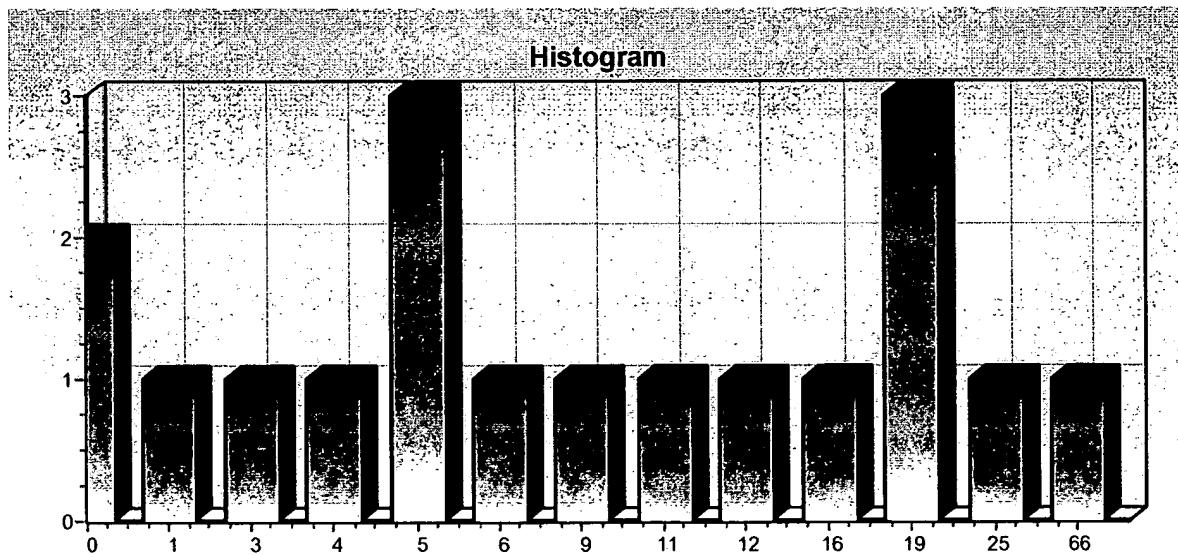
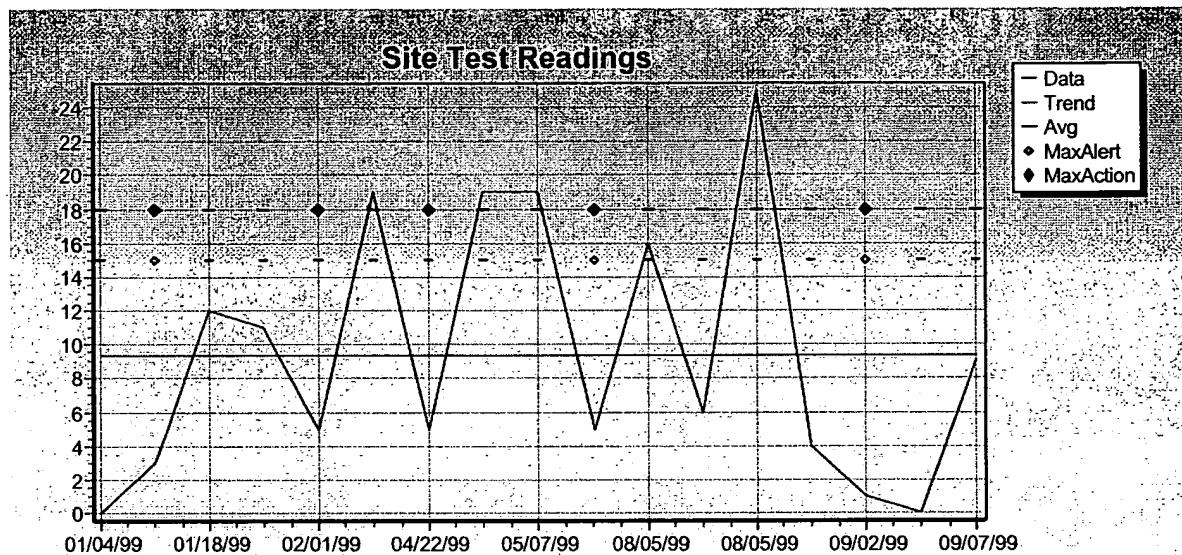
Report Date: 10/21/99

Test Site Charts

From: Oct 01 1998 To: Oct 21 1999

Room: Micro Sterility Suite

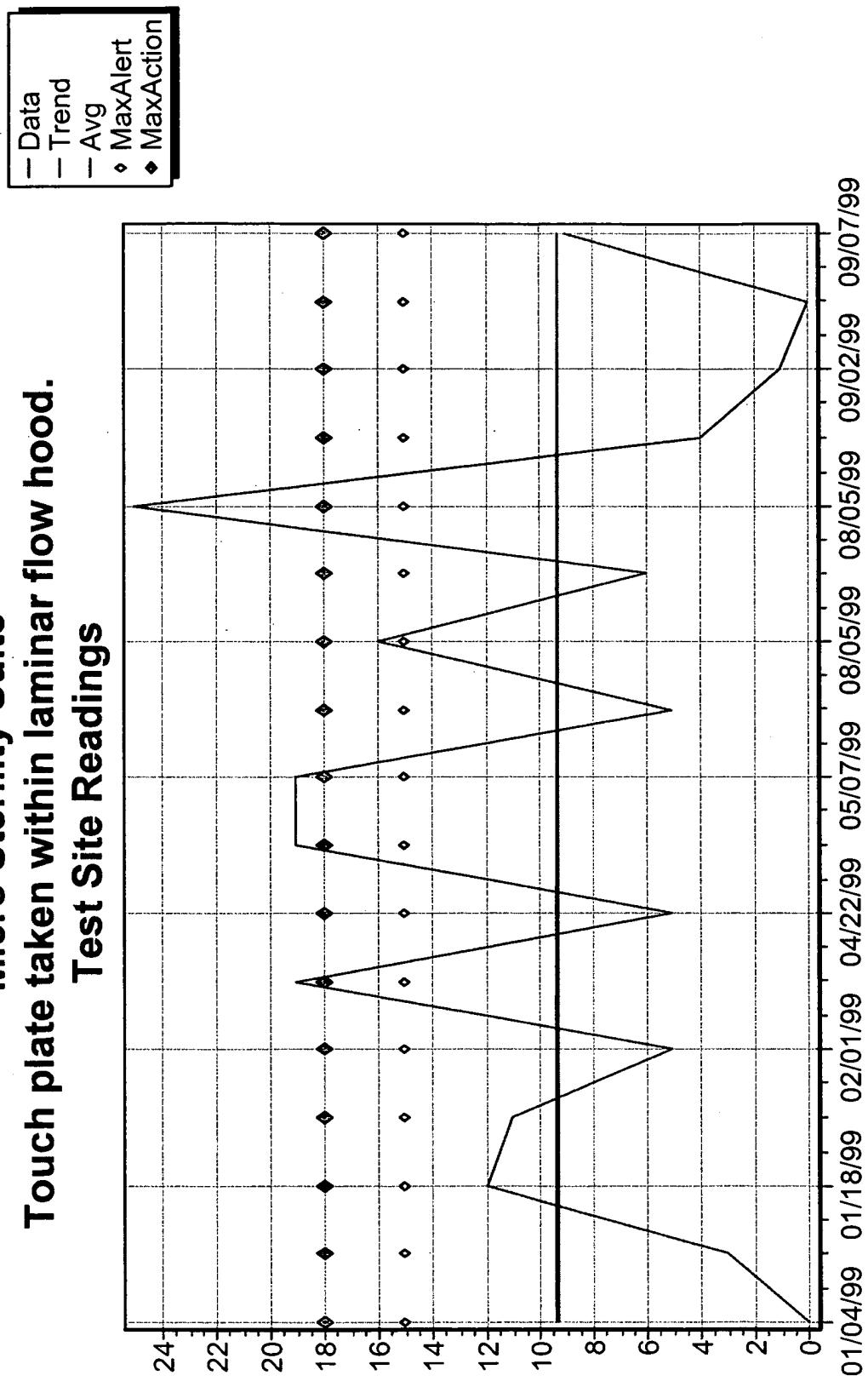
Test Site: Touch plate taken within laminar flow hood.



Micro Sterility Suite

Touch plate taken within laminar flow hood.

Test Site Readings



Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Survey Control No.

2069

Survey Date:

3/6/00

Test ID

Group:

Facility:

EMS Test Facility

Survey Shift:

Daily Tests

Product:

sqd

Lot #:

xdwx

Lot #:

Room ID: 6 RefNo MicroSterility

Room Description

Micro Sterility Suite

Rodac TSA Plate		Test ID Ref	Test ID	Test Site Description	Sample Date	Sample By	Test By	Equipment ID	Result Date	Result By	Sample ID	Room Activity	Result	Entry By	Enter Date	Exception
		E1	41	Site on work surface of laminar flow hood.	3/6/00	7:23AM	TNucci	TNucci	3/13/00	9:10AM	+S05146A	Operational	1	iradiqan	3/22/00 10:27PM	
F1	38	Floor site in front of laminar flow hood.		TNucci	3/6/00	7:05AM	1234R014	None	3/13/00	8:00AM	+S05143A	Operational	18	iradiqan	3/22/00 10:27PM	
F2	39	Floor site in doorway - room entrance.		TNucci	3/6/00	7:15AM	1234R01	None	3/13/00	9:00AM	+S05144A	Operational	22	iradiqan	3/22/00 10:27PM	
F3	40	Floor site in room corner - general cleanliness assessment.		TNucci	3/6/00	7:22AM	1234R01	None	3/13/00	9:05AM	+S05145A	Operational	8	iradiqan	3/22/00 10:27PM	

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2060

Survey Control No.

Survey Date: 3/6/00
Survey Shift: 1

Product: sqd
Lot #: xdwx

Room ID: 6

RefNo

MicroSterility
Room Description

Non Viable Particulate

Test ID Ref Test ID Test Site Description

Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result
			Sample By	Test BY	Result BY	Room Activity	Exception
			Media Lot	Equipment ID			Entered By
P1	45	Particulate count taken in room center.	3/6/00	7:15AM	3/6/00 7:15AM	+S05149A	1
			JRadigan	JRadigan	JRadigan	Operational	iradigan 3/22/00 11:15PM
			None	123444			

Touch Plate

Test ID Ref Test ID Test Site Description

Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result
			Sample By	Test BY	Result BY	Room Activity	Exception
			Media Lot	Equipment ID			Entered By
Georgel	42	Touch plate taken within laminar flow hood.	3/6/00	9:25AM	3/13/00 10:00AM	+S05147A	2
			TNucci	TNucci	JRadigan	Operational	iradigan 3/22/00 11:18PM
			1234R01				

STA Plate

Test ID Ref Test ID Test Site Description

Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result
			Sample By	Test BY	Result BY	Room Activity	Exception
			Media Lot	Equipment ID			Entered By
RLindsay	42	Touch plate taken within laminar flow hood.	3/6/00	9:26AM	3/13/00 10:00AM	+S05147B	2
			TNucci	TNucci	RLindsay	Operational	RLindsay 3/22/00 11:18PM
			1234R01				

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Reviewed By: _____
CSSC Pharmaceuticals

Date: _____

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Environmental Monitoring System

Report Date: 4/3/2000

Survey Control No. _____
Survey Date: _____
Survey Shift: _____

Facility: EMS Test Facility
Group: Daily Tests
Product: sqd
Lot #: xdwx
Date: 3/6/00

Room ID: 6 RefNo MicroSterility

Room Description
Micro Sterility Suite

Test ID Ref	Test ID	Test Site Description
	Water pH	

Test ID Ref	Test ID	Test Site Description	Water pH	Test ID Ref	Sample Date	Test Date	Result Date	Result By	Sample ID Room Activity	Result Exception	Entry By	Enter Date
					Sample By	Test By						
					Media Lot	Equipment ID						
NFI-000-1	1432	Point Of Use site at WiFi Drop			3/6/00	1:30PM	3/6/00	2:50PM	+S05150A Operational	6.3	iradiqan	3/22/00 11:18PM
					TNucci	TNucci						
					None	None						

Survey Results

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Print #: 0
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CSSC Pharmaceuticals _____
Date: _____

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2069

Survey Control No. 3/6/00
Survey Date: 1
Survey Shift:

Product: sqd
Lot #: xdwx

Room ID: 7 RefNo MicroGowning

Facility: EMS Test Facility
Group: Daily Tests

Micro Gowning Area		
Test ID Ref	Test ID	Test Site Description
R1	34	RCS airborne contamination sample taken in center of wash area.
R2	35	RCS airborne contamination sample taken in center of clean area.
P1	36	Particulate count taken in center of wash area.
P2	37	Particulate count taken in center of clean area.

Sample Date	Test Date	Result Date	Sample ID	Result	Entry By
Sample By	Test By	Result By	Room Activity	Exception	Enter Date
3/6/00 10:00AM	3/6/00 10:00AM	3/11/00 10:00AM	+S05139A	2	iradiqan 3/22/00 11:18PM
TNucci	JRadigan	None	Operational		
3/6/00 11:00AM	3/6/00 11:00AM	3/11/00 1:50PM	+S05140A	2	iradiqan 3/22/00 11:18PM
TNucci	JRadigan	Q232	Operational		
3/6/00 8:00AM	3/6/00 8:00AM	3/6/00 8:00AM	+S05141A	4	iradiqan 3/22/00 10:01PM
TNucci	TNucci	None	Operational	Alert	
3/6/00 8:05AM	3/6/00 8:05AM	3/6/00 8:05AM	+S05142A	1	iradiqan 3/22/00 10:01PM
TNucci	TNucci	None	Operational		

Environmental Monitoring System

Report Date: 4/3/2000

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Survey Contol No.

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 7 RefNo

MicroGowning

Facility: EMS Test Facility
Group: Daily Tests

Product: sqd
Lot #: xdwx

Room Description

Micro Gowning Area

Test ID Ref	Surface Swab	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result	Entry BY	Exception	Enter Date
			Sample By	Test BY	Result BY	Room Activity				
			Media Lot	Equipment ID						
S1	32	Swab sample within sink 1.	3/6/00	8:55AM	3/13/00	+S05137A	9	iradican		3/22/00 11:18PM
		- tt4ththth - 222222222222 - Reason #3	TNucci	TNucci	RWatson	Operational				
			11111111							
S2	33	Swab sample within sink 2.	3/6/00	8:56AM	3/13/00	+S05138A	2	iradican		3/22/00 11:18PM
			TNucci	TNucci	RLindsay	Operational				
			11111111							

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Survey Control No. 2069

Survey Date: 3/6/00
Survey Shift: 1

Room ID: 74 RefNo

Water System

Water Endotoxin EU/ml

Test ID Ref	Test ID	Test Site Description
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Test ID Ref	Test ID	Test Site Description	Room Description			Water System		
			Sample Date	Test Date	Result Date	Sample ID	Result	Entry By
	Sample By	Test By	Result By	Room Activity	Exception	Enter Date		
	Media Lot	Equipment ID						
D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A	3/6/00 8:23AM	3/6/00 11:05AM	3/6/00 1:35PM	+S05151A Operational	5.200	iradiagan 3/22/00 11:18PM
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room	3/6/00 8:24AM	3/6/00 9:25AM	3/6/00 1:35PM	+S05152A Operational	0.530	iradiagan 3/22/00 11:18PM

Water pH

Test ID Ref	Test ID	Test Site Description
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Test ID Ref	Test ID	Test Site Description	Room Description			Water pH		
			Sample Date	Test Date	Result Date	Sample ID	Result	Entry By
	Sample By	Test By	Result By	Room Activity	Exception	Enter Date		
	Media Lot	Equipment ID						
D1PH1	1436	Water pH at Drop 1 in Production Room A	3/6/00 10:05AM	3/6/00 10:05AM	3/6/00 4:30PM	+S05153A Operational	<0.8	iradiagan 3/22/00 11:18PM
D3PH3	1438	Water pH at Drop 3 in Production Prep Room	3/6/00 10:07AM	3/6/00 10:07AM	3/6/00 4:25PM	+S05154A Operational	4.6	iradiagan 3/22/00 11:18PM

Print #: 0
Reviewed By: _____
CSSC Pharmaceuticals

Date: _____

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2069

Survey Contol No.

3/6/00
1
Survey Date:
Survey Shift:

Room ID: 74

RefNo

Water System

Water Conductivity			Test Site Description	Test ID Ref	Test ID	Sample Date	Test Date	Test By	Result Date	Result By	Sample ID	Room Activity	Result	Entry By	Entry Date
						Sample By	Sample By	Media Lot	Result By	Exception	Room	Activity	Exception	Enter Date	
WFI=003-02	1443	Water Conductivity				3/6/00	10:45AM	TNucci	3/6/00	10:45AM	+S05155A	Operational	>4.5	iradijan	3/22/00 11:18PM
								M-002							

NQ Reason

Environmental Monitoring System

Report Date: 10/20/99

Results By Test ID

Facility: EMS Test Facility

Test ID 3 Floor between workstations approx 2 feet in front of work table.

Test ID User Ref 02 Test Type Rodac TSA Plate Site Type Floor
Room ID 5 Micro Lab2 A174

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1003	6/16/99	1	JRadigan	S-00490	Normal	1/25/99	TJoyce		0	N	N	OK
1005	7/12/99	1	JRadigan	S-00790	Normal	2/6/99	TJoyce		0	N	N	OK
1030	1/25/99	3	JRadigan	S-01890	Normal	2/6/99	TJoyce		2	N	N	OK

Test ID 4 Floor Between hood #1 and hood #2. Sample approx 2 feet in front.

Test ID User Ref 04 Test Type Rodac TSA Plate Site Type Floor
Room ID 5 Micro Lab2 A174

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1010	6/16/99	1	JRadigan	S-00210	Normal	2/6/99	TJoyce		1	N	N	OK
1029	7/12/99	3	JRadigan	S-01967	Normal	2/6/99	TJoyce		0	N	N	OK

Test ID 5 Floor in center of room.

Test ID User Ref 03 Test Type Rodac TSA Plate Site Type Floor
Room ID 5 Micro Lab2 A174

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1002	7/12/99	1	JRadigan	S-00340	Normal	1/18/99	TJoyce		5	N	N	OK
1038	6/16/99	1	JRadigan	S-00940	Normal	2/6/99	TJoyce		7	N	N	OK

Test ID 6 Floor in doorway / room entrance

Test ID User Ref 01 Test Type Rodac TSA Plate Site Type Floor
Room ID 5 Micro Lab2 A174

Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1002	1/25/99	1	JRadigan	S-00339	Normal	1/25/99	TJoyce		13	N	N	OK
1003	7/12/99	1	JRadigan	S-00489	Normal	7/12/99	TJoyce		13	N	N	OK
1005	3/22/99	1	JRadigan	S-00789	Normal	3/22/99	TJoyce		3	N	N	OK
1038	6/16/99	1	JRadigan	S-00939	Normal	6/16/99	TJoyce		6	N	N	OK

Environmental Monitoring System

Report Date: 10/20/99

Results By Test ID

Facility: EMS Test Facility

Test ID 8 Site on work surface of laminar hood 1.

Test ID User Ref 05 Test Type Rodac TSA Plate Site Type Critical Surface
Room ID 5 Micro Lab2 A174

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	6/16/99	1	JRadigan	S-00015	Normal	1/11/99	TJoyce	6	N	Y	OK
1038	7/12/99	1	JRadigan	S-00941	Normal	1/25/99	TJoyce	5	N	N	OK

Test ID 10 Personnel touch plate.

Test ID User Ref T1 Test Type Touch Plate Site Type Glove
Room ID 5 Micro Lab2 A174

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00020	Normal	1/11/99	TJoyce	6	N	N	OK
1010	2/19/99	1	JRadigan	S-00215	Normal			N	N		
1002	1/11/99	1	JRadigan	S-00345	Normal	1/18/99	TJoyce	16	N	N	> Action
1003	1/18/99	1	JRadigan	S-00495	Normal	1/25/99	TJoyce	1	N	Y	OK
1004	1/25/99	1	JRadigan	S-00645	Normal	2/1/99	TJoyce	7	N	N	OK
1005	2/1/99	1	JRadigan	S-00795	Normal	2/8/99	TJoyce	2	N	N	OK
1038	4/6/99	1	JRadigan	S-00945	Normal			N	N		
1029	2/19/99	3	JRadigan	S-01962	Normal			N	N		
1030	2/19/99	3	JRadigan	S-01977	Normal			N	N		

Test ID 11 Airborne contamination STA plate in center of room.

Test ID User Ref S1 Test Type STA Plate Site Type Counter
Room ID 5 Micro Lab2 A174

Survey#	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status
1001	1/4/99	1	JRadigan	S-00021	Normal	1/9/99	TJoyce	28	N	N	> Action
1010	2/19/99	1	JRadigan	S-00216	Normal			N	N		
1002	1/11/99	1	JRadigan	S-00346	Normal	1/16/99	TJoyce	25	N	N	> Action
1003	1/18/99	1	JRadigan	S-00496	Normal	1/23/99	TJoyce	29	N	N	> Action
1004	1/25/99	1	JRadigan	S-00646	Normal	1/30/99	TJoyce	12	N	N	OK
1005	2/1/99	1	JRadigan	S-00796	Normal	2/6/99	TJoyce	10	N	N	OK
1038	4/6/99	1	JRadigan	S-00946	Normal			N	N		
1030	2/19/99	3	JRadigan	S-01892	Normal			N	N		
1029	2/19/99	3	JRadigan	S-01969	Normal			N	N		
2007	8/5/99	1	JRadigan	+S04130	Normal			N	N		

Environmental Monitoring System

Report Date: 10/20/99

Results By Test ID

Facility: EMS Test Facility

Test ID 12 Particulate count taken between laminar flow hoods.

Test ID	User Ref	P1	Test Type	Non Viable Particulate	Site Type	Counter						
Room ID		5	Micro Lab2 A174									
Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1001	1/4/99	1	JRadigan	S-00022	Normal	1/4/99	TJoyce		1	N	N	OK
1010	2/19/99	1	JRadigan	S-00217	Normal					N	N	
1002	1/11/99	1	JRadigan	S-00347	Normal	1/11/99	TJoyce		0	N	N	OK
1003	1/18/99	1	JRadigan	S-00497	Normal	1/18/99	TJoyce		5	N	N	> Action
1004	1/25/99	1	JRadigan	S-00647	Normal	1/25/99	TJoyce		5	N	N	> Action
1005	2/1/99	1	JRadigan	S-00797	Normal	2/1/99	TJoyce		6	N	N	> Action
1038	4/6/99	1	JRadigan	S-00947	Normal					N	N	
1030	2/19/99	3	JRadigan	S-01893	Normal					N	N	
1029	2/19/99	3	JRadigan	S-01970	Normal					N	N	
2007	8/5/99	1	JRadigan	+S04131	Normal		JRadigan		9	N	N	> Action

Test ID 13 Floor site in doorway - room entrance.

Test ID	User Ref	F1	Test Type	Rodac TSA Plate	Site Type	Floor						
Room ID		4	Micro Lab 1									
Survey #	Test Date	Shift	Test By	SampleID	Room Activity	Read Date	Read By	Reading	TNTC	NoTest	Rslt Status	
1001	1/4/99	1	JRadigan	S-00001	Normal	1/11/99	TJoyce		23	N	N	OK
1002	1/11/99	1	JRadigan	S-00151	Normal	1/18/99	TJoyce		5	N	N	OK
1010	2/19/99	1	JRadigan	S-00197	Normal					N	N	
1003	1/18/99	1	JRadigan	S-00476	Normal	1/25/99	TJoyce		21	N	N	OK
1004	1/25/99	1	JRadigan	S-00626	Normal	2/1/99	TJoyce		2	N	N	OK
1005	2/1/99	1	JRadigan	S-00776	Normal	2/8/99	TJoyce		9	N	N	OK
1011	2/19/99	1	JRadigan	S-01786	Normal					N	N	
1029	2/19/99	3	Callahan	S-01889	Normal					N	N	
1038	4/6/99	1	JRadigan	S-01927	Normal					N	N	
1030	2/19/99	3	JRadigan	S-01973	Normal					N	N	
1061	5/18/99	1	rlindsay	+S03042	Normal	5/25/99	JRadigan		35	N	N	> Action

Environmental Monitoring System

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Survey Test Log

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
6/25/1998	526	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
7/2/1998	527	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
7/9/1998	528	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
7/16/1998	529	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
7/23/1998	530	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
7/30/1998	531	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
8/6/1998	532	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
8/13/1998	533	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
8/20/1998	534	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
8/27/1998	535	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
9/3/1998	536	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
9/10/1998	537	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
9/17/1998	538	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
9/24/1998	539	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
10/1/1998	540	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
10/8/1998	541	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
10/15/1998	542	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
10/22/1998	543	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
10/29/1998	544	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
11/5/1998	545	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
11/12/1998	546	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
11/19/1998	547	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
11/26/1998	548	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
12/3/1998	549	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
12/10/1998	550	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
1/1/1999	501	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
1/8/1999	502	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
1/15/1999	503	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
1/22/1999	504	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
1/29/1999	505	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
2/5/1999	506	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
2/12/1999	507	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
2/19/1999	508	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
2/26/1999	509	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
3/5/1999	510	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
3/12/1999	511	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
3/19/1999	512	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed
3/26/1999	513	4	Production Room Daily	1	None	None	0	0	0	13 VGalliani	Closed

Environmental Monitoring System

Report Date: 10/20/1999

Survey Test Log

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
4/2/1998	514	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/9/1998	515	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/16/1998	516	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/23/1998	517	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
4/30/1998	518	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/7/1998	519	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/14/1998	520	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/21/1998	521	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
5/28/1998	522	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/4/1998	523	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/11/1998	524	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
6/18/1998	525	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/17/1998	551	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
12/24/1998	552	4	Production Room Daily	1	None	None	0	0	13	VGalliani	Closed
1/4/1999	1001	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/11/1999	1002	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/18/1999	1003	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
1/25/1999	1004	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
2/1/1999	1005	2	Weekly Tests	1	None	None	0	0	150	VGalliani	Closed
2/17/1999	1007	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
2/19/1999	1008	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
	1009	4	Production Room Daily	1	None	None	0	0	13	JRadigan	In Proc
	1010	2	Weekly Tests	1	None	None	0	0	149	JRadigan	Open
	1012	4	Production Room Daily	1	None	None	0	0	13	JRadigan	Open
	1013	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1014	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1015	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1016	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1017	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1018	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1019	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1020	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1021	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1022	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1023	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1024	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1025	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1026	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open

Environmental Monitoring

System

Report Date: 10/20/1999

Survey Test Log

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
2/19/1999	1027	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1028	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1029	0	Released By Test or Room	1	None	None	0	0	15	JRadigan	Open
	1030	0	Released By Test or Room	1	None	None	17	17	17	JRadigan	In Proc
	1031	3	Daily Tests	1	None	None	0	0	4	JRadigan	Open
	1032	0	Released By Test or Room	1	None	None	0	0	7	JRadigan	Open
	1033	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1034	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
2/23/1999	1035	3	Insert Group Name Here	1	None	None	0	0	13	JRadigan	Open
	1036	4	Insert Group Name Here	1	None	None	0	0	7	JRadigan	Open
2/26/1999	1037	3	Insert Group Name Here	1	None	None	0	0	149	JRadigan	Open
4/6/1999	1038	2	Insert Group Name Here	1	None	None	0	0	7	JRadigan	Closed
4/22/1999	1039	3	Insert Group Name Here	1	None	None	0	0	6	JRadigan	Closed
	1040	3	Insert Group Name Here	1	None	None	0	0	4	JRadigan	Closed
	1041	3	Insert Group Name Here	1	None	None	0	0	6	JRadigan	Closed
	1042	3	Insert Group Name Here	1	None	None	0	0	6	JRadigan	In Proc
	1043	3	Insert Group Name Here	1	None	None	0	0	5	JRadigan	In Proc
	1044	3	Insert Group Name Here	1	None	None	0	0	7	JRadigan	In Proc
	1045	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
4/30/1999	1046	3	Daily Tests	1	None	None	0	0	6	JRadigan	In Proc
5/7/1999	1047	3	Daily Tests	1	None	None	0	0	7	JRadigan	In Proc
	1048	3	Daily Tests	1	None	None	0	0	5	JRadigan	Closed
	1049	3	Daily Tests	1	None	None	0	0	7	JRadigan	In Proc
	1050	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1051	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1052	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1053	3	Daily Tests	1	None	None	0	0	7	JRadigan	In Proc
	1054	3	Daily Tests	1	None	None	0	0	7	JRadigan	Open
	1055	3	Production Room Daily Tests	1	None	None	0	0	13	Jradigan	Open
7/13/1999	1504	4	Production Room Daily Tests	1	rrrr	rrrr	0	0	13	Jradigan	Open
	1505	3	Daily Tests	1	None	None	0	0	13	Jradigan	Open
	1507	3	Daily Tests	1	ttt	ttt	0	0	13	Jradigan	Open
	1509	3	Daily Tests	1	gbnnnn	gbnnnn	0	0	13	Jradigan	Open
7/22/1999	2000	3	Daily Tests	1	uuuy	tituituitu	0	0	13	Jradigan	In Proc
7/29/1999	2001	3	Daily Tests	1	666666	666666	0	0	12	Jradigan	In Proc
8/5/1999	2004	3	Daily Tests	1	cvcvcv	cvcvcv	0	0	14	Jradigan	In Proc
	2005	3	Daily Tests	1	ouioiuo	ouioiuo	0	0	15	Jradigan	In Proc

Environmental Monitoring

System

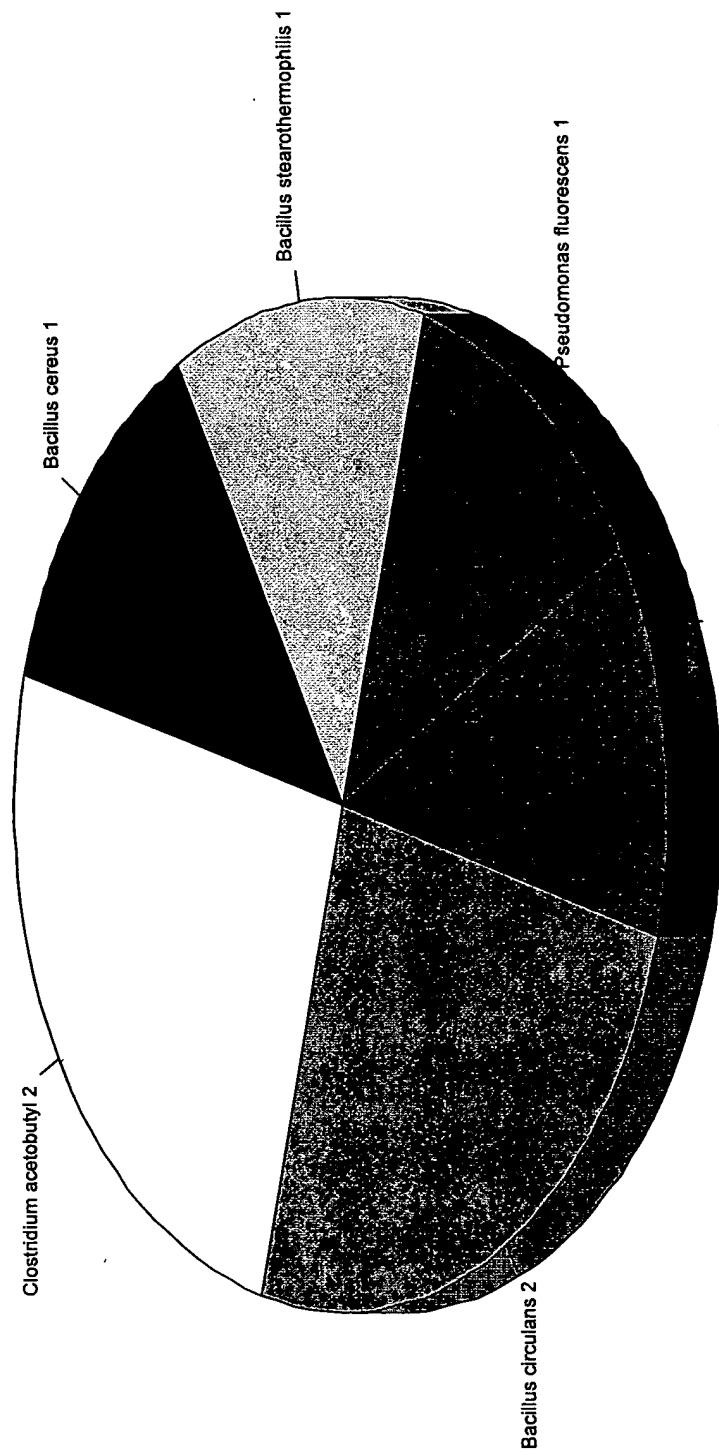
Report Date: 10/20/1999

Survey Test Log

Facility: EMS Test Facility

Test Date	Survey #	Group ID	Group Description	Shift	Product	Lot Number	Incomplete Test Site	Open Readings	Total Tests	Init By	Status
8/5/1999	2006	3	Daily Tests	1	efief	sfsfsd		6	8	13	radigan
	2007	0	Manually Created Survey	1	ththth	rthrhr		3	3	3	radigan
8/10/1999	2008	3	Daily Tests	1	None	None		13	13	13	radigan
	2009	3	Daily Tests	1	None	None		13	13	13	radigan
8/25/1999	2010	3	Daily Tests	1	None	None		14	14	13	radigan
	2011	3	Daily Tests	2	None	None		15	15	15	radigan
9/2/1999	2012	3	Daily Tests	1	hjfhgjhhf	jutuyfuy		6	9	14	radigan
9/7/1999	2013	3	Daily Tests	1	jtujtujy	tiutuitui		7	13	14	radigan
10/14/1999	2014	3	Daily Tests	1	PWF110ml	1234-66JK7		14	14	14	radigan
10/19/1999	2015	3	Daily Tests	1	1313131	11111-44		13	13	14	radigan

Organism Summary



Environmental Monitoring System

Organism Identification Listing

<u>Report Date:</u>	<u>Organism Type</u>	<u>Genus/Species Name</u>	<u>TestID</u>	<u>Sample ID</u>	<u>Test ID Description</u>	<u>Objectable</u>
1/16/2002						
00-January						
1/20/00	Bacteria	Bacillus circulans	1443	+S04606A	Water Conductivity	N
00-August						
8/5/00	Bacteria	Bacillus circulans	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
8/5/00	Bacteria	Clostridium acetobutyli	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
8/5/00	Mold	Mold NOD	35	+S05316A	RCS airborne contamination sample taken in center of clean area.	N
01-February						
2/20/01	Bacteria	Clostridium acetobutyli	17	+S07802A	Floor site in center of room.	N
2/20/01	Other	Bacillus cereus	18	+S07803A	Site on work surface of laminar flow hood.	N
01-June						
6/5/01	Bacteria	Bacillus stearothermophilis	18	+S08529A	Site on work surface of laminar flow hood.	N
01-December						
12/5/01	Bacteria	Pseudomonas fluorescens	16	SB000002A	Floor site in front of sinks.	N

Environmental Monitoring System

Two Readings

Report Period - From: 01/01/2001 To: 01/16/2002

Report Date: 1/16/2002 Facility: EMS Test Facility

Sample ID: +S08483A Selected Reading: None

Sample ID: +S08524A Selected Reading: Reading 2

Reading 1: 10 Reading 1 Date: 11/1/2001 9:00:00AM Reading 1 By: TJoyce

Reading 2: 5 Reading 2 Date: 11/1/2001 9:00:00AM Reading 2 By: TJoyce

Average of the Two Readings: 8

Sample ID: +S08525A Selected Reading: Average

Reading 1: 14 Reading 1 Date: 12/1/2001 6:00:00AM Reading 1 By: VGalliani

Reading 2: 15 Reading 2 Date: 12/1/2001 6:00:00AM Reading 2 By: VGalliani

Average of the Two Readings: 14

Sample ID: +S08526A Selected Reading: Average

Reading 1: 12 Reading 1 Date: 12/2/2001 7:00:00AM Reading 1 By: VGalliani

Reading 2: 17 Reading 2 Date: 12/2/2001 7:00:00AM Reading 2 By: VGalliani

Average of the Two Readings: 14

Sample ID: +S08527A Selected Reading: None

Sample ID: SB000002A Selected Reading: None

Sample ID: SB000004A Selected Reading: Reading 2

Reading 1: 10 Reading 1 Date: 12/5/2001 1:00:00PM Reading 1 By: TJoyce

Reading 2: 5 Reading 2 Date: 12/5/2001 1:00:00PM Reading 2 By: TJoyce

Average of the Two Readings: 8

**Environmental Monitoring
System**

Multiple Samples

Report Period - From: 01/01/2001

To: 01/16/2002

Report Date: 1/16/2002 Facility: EMS Test Facility

Sample ID: +S08533A Number of Package Units: 3.00 Number of Samples / Unit: 4.00

	Package Unit 1	Package Unit 2	Package Unit 3
Sample 1	12	12	6
Sample 2	2	4	8
Sample 3	12	5	9
Sample 4	6	3	12

Average / Mean: 8

Environmental Monitoring System

Summary of Reviewed Surveys

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Survey Number: 1001		
+S05313A	JRadigan	4/21/1999 6:29:59AM
+S05314A	JRadigan	4/25/1999 8:29:59PM
+S05315A	JRadigan	4/23/1999 5:29:59PM
+S05316A	JRadigan	4/22/1999 1:29:59AM
+S05317A	JRadigan	4/20/1999 6:29:59AM
+S05318A	JRadigan	4/15/1999 8:29:59AM
+S05319A	JRadigan	4/28/1999 7:29:59AM
+S05320A	JRadigan	4/27/1999 8:29:59AM
+S05321A	JRadigan	4/25/1999 10:29:59AM
+S05322A	JRadigan	4/27/1999 8:29:59AM
+S05323A	JRadigan	4/24/1999 12:29:59AM
+S05323B	JRadigan	4/26/1999 2:29:59PM
+S05324A	JRadigan	4/24/1999 6:29:59PM
+S05325A	JRadigan	4/15/1999 2:29:59AM
+S05326A	JRadigan	4/20/1999 10:29:59AM
+S05327A	JRadigan	4/19/1999 10:29:59AM
+S05328A	JRadigan	4/18/1999 3:29:59AM
+S05329A	JRadigan	4/19/1999 6:29:59PM
+S05330A	JRadigan	4/18/1999 10:29:59PM
+S05331A	JRadigan	4/19/1999 7:29:59AM
+S05332A	JRadigan	4/23/1999 1:29:59PM
+S05333A	JRadigan	4/24/1999 7:29:59AM
+S05334A	JRadigan	4/24/1999 4:29:59PM
+S05335A	JRadigan	4/23/1999 7:29:59AM
+S05336A	JRadigan	4/24/1999 1:29:59PM
+S05337A	glevinson	1/9/2002 1:59:12PM
+S05338A	JRadigan	4/27/1999 6:29:59PM
+S05339A	JRadigan	4/28/1999 1:29:59AM
+S05340A	JRadigan	4/25/1999 9:29:59PM
+S05341A	JRadigan	4/20/1999 4:29:59PM
+S05342A	JRadigan	4/23/1999 5:29:59PM
+S05343A	JRadigan	4/15/1999 2:29:59AM
+S05344A	JRadigan	4/27/1999 10:29:59PM
+S05345A	JRadigan	4/27/1999 7:29:59AM
+S05346A	JRadigan	4/24/1999 2:29:59AM
+S05347A	JRadigan	4/24/1999 4:29:59AM
+S05348A	JRadigan	4/26/1999 11:29:59AM
+S05349A	JRadigan	4/24/1999 9:29:59PM
+S05350A	JRadigan	4/22/1999 9:29:59PM
+S05351A	JRadigan	4/26/1999 3:29:59PM
+S05351B	JRadigan	4/27/1999 12:29:59PM
+S05352A	JRadigan	4/24/1999 6:29:59PM
+S05353A	JRadigan	4/19/1999 1:29:59AM

Environmental Monitoring System

Summary of Reviewed Surveys

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Survey Number: 1002		
+S05354A	JRadigan	4/30/1999 6:29:59PM
+S05355A	JRadigan	4/29/1999 1:29:59AM
+S05356A	JRadigan	5/2/1999 1:29:59PM
+S05357A	JRadigan	4/28/1999 8:29:59PM
+S05358A	JRadigan	4/24/1999 4:29:59PM
+S05359A	JRadigan	4/21/1999 9:29:59PM
+S05360A	JRadigan	4/30/1999 5:29:59AM
+S05361A	JRadigan	4/28/1999 3:29:59AM
+S05362A	JRadigan	4/29/1999 10:29:59AM
+S05363A	JRadigan	5/3/1999 1:29:59AM
+S05364A	JRadigan	4/28/1999 4:29:59AM
+S05364B	JRadigan	4/29/1999 5:29:59PM
+S05365A	JRadigan	5/1/1999 3:29:59AM
+S05366A	JRadigan	4/23/1999 4:29:59AM
+S05367A	JRadigan	4/27/1999 1:29:59AM
+S05368A	JRadigan	4/24/1999 9:29:59PM
+S05369A	JRadigan	4/24/1999 9:29:59PM
+S05370A	JRadigan	4/22/1999 4:29:59PM
+S05371A	JRadigan	4/25/1999 7:29:59PM
+S05372A	JRadigan	4/27/1999 3:29:59AM
+S05373A	JRadigan	5/2/1999 4:29:59PM
+S05374A	JRadigan	4/29/1999 2:29:59PM
+S05375A	JRadigan	4/28/1999 12:29:59PM
+S05376A	JRadigan	5/3/1999 12:29:59PM
+S05377A	JRadigan	4/28/1999 12:29:59PM
+S05378A	JRadigan	5/1/1999 7:29:59PM
+S05379A	JRadigan	5/1/1999 10:29:59PM
+S05380A	JRadigan	5/3/1999 5:29:59AM
+S05381A	JRadigan	5/2/1999 5:29:59AM
+S05382A	JRadigan	4/26/1999 9:29:59PM
+S05383A	JRadigan	4/28/1999 10:29:59AM
+S05384A	JRadigan	4/26/1999 5:29:59AM
+S05385A	JRadigan	5/2/1999 8:29:59PM
+S05386A	JRadigan	4/28/1999 10:29:59AM
+S05387A	JRadigan	4/30/1999 6:29:59AM
+S05388A	JRadigan	4/29/1999 6:29:59AM
+S05389A	JRadigan	5/2/1999 7:29:59PM
+S05390A	JRadigan	5/4/1999 8:29:59PM
+S05391A	JRadigan	5/1/1999 10:29:59AM
+S05392A	JRadigan	5/4/1999 2:29:59AM
+S05392B	JRadigan	4/28/1999 3:29:59PM
+S05393A	JRadigan	4/27/1999 2:29:59PM
+S05394A	JRadigan	4/27/1999 10:29:59PM

Environmental Monitoring System

Summary of Reviewed Surveys

Report Date: 1/16/2002

Sample ID	Review By	Review Date
Survey Number: 1003		
+S05395A	JRadigan	5/12/1999 5:30:00AM
+S05396A	JRadigan	5/6/1999 5:30:00PM
+S05397A	JRadigan	5/8/1999 5:30:00PM
+S05398A	JRadigan	5/7/1999 7:30:00PM
+S05399A	JRadigan	5/4/1999 2:30:00AM
+S05400A	JRadigan	4/29/1999 9:30:00AM
+S05401A	JRadigan	5/5/1999 9:30:00AM
+S05402A	JRadigan	5/10/1999 9:30:00PM
+S05403A	JRadigan	5/7/1999 10:30:00PM
+S05404A	JRadigan	5/5/1999 7:30:00AM
+S05405A	JRadigan	5/10/1999 10:30:00AM
+S05405B	JRadigan	5/6/1999 12:30:00AM
+S05406A	JRadigan	5/6/1999 4:30:00PM
+S05407A	JRadigan	4/30/1999 4:30:00PM
+S05408A	JRadigan	5/4/1999 8:30:00AM
+S05409A	JRadigan	4/29/1999 1:30:00AM
+S05410A	JRadigan	5/3/1999 12:30:00AM
+S05411A	JRadigan	4/27/1999 11:30:00PM
+S05412A	JRadigan	4/30/1999 4:30:00AM
+S05413A	JRadigan	5/3/1999 2:30:00AM
+S05414A	JRadigan	5/5/1999 11:30:00PM
+S05415A	JRadigan	5/12/1999 4:30:00AM
+S05416A	JRadigan	5/5/1999 9:30:00AM
+S05417A	JRadigan	5/5/1999 5:30:00AM
+S05418A	JRadigan	5/11/1999 6:30:00PM
+S05419A	JRadigan	5/6/1999 9:30:00AM
+S05420A	JRadigan	5/5/1999 2:30:00PM
+S05421A	JRadigan	5/4/1999 10:30:00PM
+S05422A	JRadigan	5/6/1999 11:30:00PM
+S05423A	JRadigan	5/4/1999 9:30:00AM
+S05424A	JRadigan	5/10/1999 1:30:00AM
+S05425A	JRadigan	4/30/1999 12:30:00AM
+S05426A	JRadigan	5/8/1999 2:30:00PM
+S05427A	JRadigan	5/12/1999 2:30:00AM
+S05428A	JRadigan	5/9/1999 3:30:00AM
+S05429A	JRadigan	5/11/1999 12:30:00AM
+S05430A	JRadigan	5/10/1999 4:30:00PM
+S05431A	JRadigan	5/10/1999 2:30:00PM
+S05432A	JRadigan	5/8/1999 2:30:00PM
+S05433A	JRadigan	5/11/1999 7:30:00PM
+S05433B	JRadigan	5/5/1999 1:30:00PM
+S05434A	JRadigan	5/9/1999 3:30:00PM
+S05435A	JRadigan	5/1/1999 10:30:00AM

Sample Operational Documents

Environmental Monitoring System

Report Date: 4/3/2000

Survey Control No. 2076

Survey Date: 4/3/2000

Survey Shift: 1

Room ID: 6

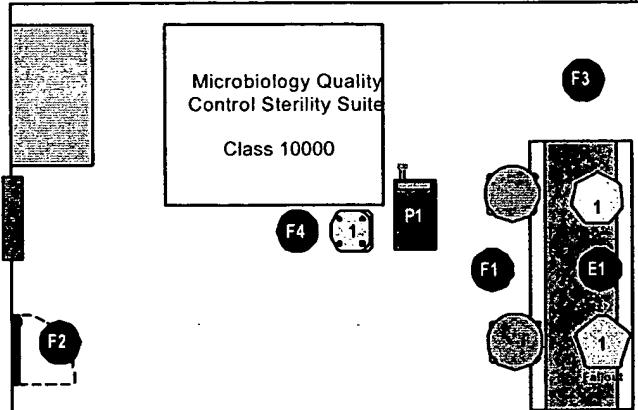
RefNo MicroSterility

Room Description

Micro Sterility Suite

Facility: EMS Test Facility

Group Daily Tests



Activity Level Static
 Operational

Non Viable Particulate			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type	Sample By	On Test By	
45	P1	Counter			Equip _____
		Particulate count taken in room center.			Read _____
			+S05265A		
Rodac TSA Plate			Sample Date / Time	On Test Date / Time	Equipment ID/ Media/ Lot
Test ID:	Test Ref	Site Type	Sample By	On Test By	
38	F1	Floor			Equip _____
		Floor site in front of laminar flow hood.			Media _____
			+S05259A		
39	F2	Floor			Equip _____
		Floor site in doorway - room entrance.			Media _____
			+S05260A		
40	F3	Floor			Equip _____
		Floor site in room corner - general cleanliness assessment.			Media _____
			+S05261A		
41	E1	Critical Surface			Equip _____
		Sit on work surface of laminar flow hood.			Media _____
			+S05262A		

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Review By: _____

Date: _____

CSSC Pharmaceuticals

Environmental Monitoring Syst m

Report Date: 4/3/2000

Survey Worksheet

Survey Contol No. 2076 Facility: EMS Test Facility
 Survey Date: 4/3/2000 Group Daily Tests
 Survey Shift: 1

STA Plate			Sample Date / Time	On Test Date / Time	Equipment ID/ Media Lot
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
44	1	Counter			Equip _____ Media _____
STA airborne contamination sample taken in room center. +S05264A					
Touch Plate			Sample Date / Time	On Test Date / Time	Emp ID/ Media Lot
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
42	TP1	Glove			Emp ID _____ Media _____
Touch plate taken within laminar flow hood. +S05263A					
42	TP1	Glove			Emp ID _____ Media _____
Touch plate taken within laminar flow hood. +S05263B					
Water pH			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
1432	WFI-000-1	Water			Equip _____ Read _____
Point Of Use site at WFI Drop +S05266A					

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Review By: _____ Date: _____
 CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No. 2076

Survey Date: 4/3/2000

Survey Shift: 1

Room ID: 7

RefNo MicroGowning

Room Description

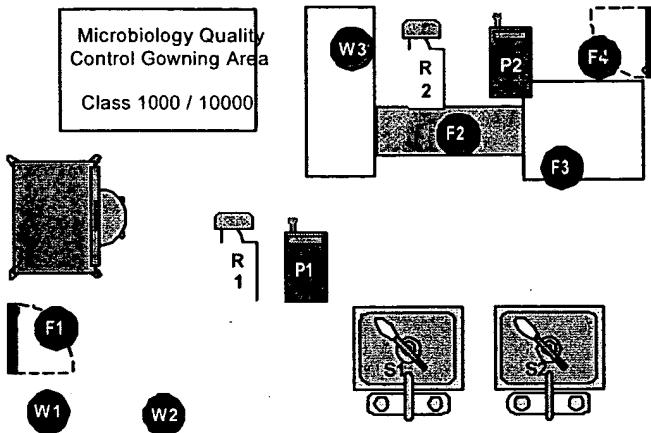
Micro Gowning Area

Facility: EMS Test Facility

Group Daily Tests

Survey Worksheet

Microbiology Quality Control Gowning Area
Class 1000 / 10000



Activity Level Static Operational

Non Viable Particulate			Sample Date / Time	On Test Date / Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type	Sample By	On Test By	
36	P1	Counter			Equip _____ Read _____
		Particulate count taken in center of wash area.			
			+S05257A		
37	P2	Counter			Equip _____ Read _____
		Particulate count taken in center of clean area.			
			+S05258A		
RCS Air Sample			Sample Date / Time	On Test Date / Time	Equipment ID/ Media Lot
Test ID:	Test Ref	Site Type	Sample By	On Test By	
34	R1	Counter			Equip _____ Media _____
		RCS airborne contamination sample taken in center of wash area.			
			+S05255A		
35	R2	Counter			Equip _____ Media _____
		RCS airborne contamination sample taken in center of clean area.			
			+S05256A		

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Review By: _____

Date: _____

CSSC Pharmaceuticals

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Environmental Monitoring System

Survey Worksheet

Report Date: 4/3/2000

Survey Control No. **2076** Facility: **EMS Test Facility**

Survey Date: 4/3/2000 Group **Daily Tests**

Survey Shift: 1

Surface Swab

Sample Date /

Time

Sample By

On Test Date /

Time

On Test By

Equipment ID /

Media Lot

Test ID:	Test Ref	Site Type	Sample Date /	On Test Date /	Equipment ID /
		Test Description	Time	Time	Media Lot
32	S1	Work Surface			Equip _____
		Swab sample within sink 1.			Media _____
			+S05253A		
33	S2	Work Surface			Equip _____
		Swab sample within sink 2.			Media _____
			+S05254A		

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Review By: _____

Date: _____

CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No. **2076**

Survey Date: 4/3/2000

Survey Shift: 1

Room ID: **74**

RefNo **Water System**

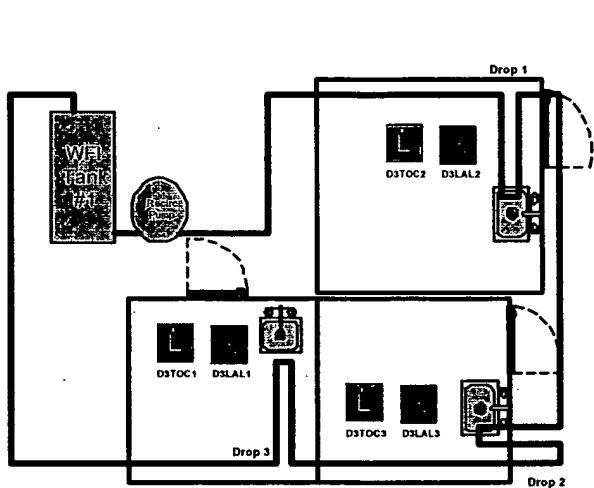
Room Description

Water System

Facility: **EMS Test Facility**

Group **Daily Tests**

Survey Worksheet



Activity Level

Static
 Operational

Water Conductivity			Sample Date / Time	On Test Date / Time	Equipment ID / Reading
Test ID:	Test Ref	Site Type / Test Description	Sample By	On Test By	
1443	WFI=003-02	Water Water Conductivity			Equip _____ Read _____
			+S05271A		
Water Endotoxin EU/ml			Sample Date / Time	On Test Date / Time	Equipment ID / Reading
Test ID:	Test Ref	Site Type / Test Description	Sample By	On Test By	
1433	D1LAL1	Water Water Endotoxin at Drop 1 in Production Room A			Equip _____ Read _____
			+S05267A		
1435	D3LAL3	Water Water Endotoxin test at Drop 3 in Production Prep Room			Equip _____ Read _____
			+S05268A		

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Review By: _____ Date: _____
CSSC Pharmaceuticals

Environmental Monitoring System

Report Date: 4/3/2000

Survey Contol No. **2076**

Survey Date: 4/3/2000

Survey Shift: 1

Survey Worksheet

Water pH			Sample Date/ Time	On Test Date/ Time	Equipment ID/ Reading
Test ID:	Test Ref	Site Type Test Description	Sample By	On Test By	
1436	D1PH1	Water			Equip _____ Read _____
		Water pH at Drop 1 in Production Room A	+S05269A		
1438	D3PH3	Water			Equip _____ Read _____
		Water pH at Drop 3 in Production Prep Room	+S05270A		

Print # 0001

2 of 2

C:\EMS214\reports\SurveyWorksheet3.rpt

Review By: _____

Date: _____

CSSC Pharmaceuticals

Survey #	Room	Test Type	Test ID
2076	7	Surface Swab	32

S1

By _____

* , S05252A *
+S05253A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	7	Surface Swab	33

S2

By _____

* , S05254A *
+S05254A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	7	RCS Air Sample	34

R1

By _____

* , S05255A *
+S05255A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	7	RCS Air Sample	35

R2

By _____

* , S05256A *
+S05256A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	7	Non Viable Particulate	36

P1

By _____

* , S05257A *
+S05257A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	7	Non Viable Particulate	37

P2

By _____

* , S05258A *
+S05258A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	38

F1

By _____

* , S05259A *
+S05259A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	39

F2

By _____

* , S05260A *
+S05260A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	40

F3

By _____

* , S05261A *
+S05261A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Rodac TSA Plate	41

E1

By _____

* , S05262A *
+S05262A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Touch Plate	42

TP1

By _____

* , S05262A *
+S05263A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Touch Plate	42

TP1

By _____

* , S05262R *
+S05263B Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	STA Plate	44

1

By _____

* , S05264A *
+S05264A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Non Viable Particulate	45

P1

By _____

* , S05265A *
+S05265A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	6	Water pH	1432

WFI-000-1

By _____

* , S05266A *
+S05266A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	74	Water Endotoxin EU/ml	1433

D1LAL1

By _____

* , S05267A *
+S05267A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	74	Water Endotoxin EU/ml	1435

D3LAL3

By _____

* , S05268A *
+S05268A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	74	Water pH	1436

D1PH1

By _____

* , S05269A *
+S05269A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	74	Water pH	1438

D3PH3

By _____

* , S05270A *
+S05270A Date: 4/3/00
 Time:

Survey #	Room	Test Type	Test ID
2076	74	Water Conductivity	1443

WFI=003-02

By _____

* , S05271A *
+S05271A Date: 4/3/00
 Time:

Environmental Monitoring System

Test Reading Worksheet

Report Date: 4/3/2000

RCS Air Sample

Control	Test ID	Test Description	Sample ID	Read Date Time:	Result:
	Scheduled Read Date:	Room Description	Alert Limit	Read By:	Ref Doc:
	Ref #	Test Type	Action Limit		
2073	Group	Daily Tests			
2073	34	RCS airborne contamination sample taken in center of wash area.	+S05198A		
	3/21/00 8:54AM		40		
	R1	Micro Gowning Area	50		
		RCS Air Sample			
2073	35	RCS airborne contamination sample taken in center of clean area.	+S05199A		
	3/21/00 10:30AM		30		
	R2	Micro Gowning Area	40		
		RCS Air Sample			

Print #: 0001

Reviewed By: _____ Date: _____

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CSSC Pharmaceuticals

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Environmental Monitoring System

Test Reading Worksheet

Report Date: 4/3/2000

RCS Air Sample

Control	Test ID	Test Description	Sample ID	Read Date Time:	Result:
	Scheduled Read Date:	Room Description	Alert Limit	Read By:	Ref Doc:
	Ref #	Test Type	Action Limit		
2075	Group	Daily Tests			
2075	34	RCS airborne contamination sample taken in center of wash area.	+S05236A	40	
	4/3/00 9:30AM	R1 Micro Gowning Area	50		
		RCS Air Sample			
2075	35	RCS airborne contamination sample taken in center of clean area.	+S05237A	30	
	4/3/00 9:45AM	R2 Micro Gowning Area	40		
		RCS Air Sample			

Print #: 0001

Reviewed By: _____ Date: _____

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CSSC Pharmaceuticals

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Environmental Monitoring System

Test Reading Worksheet

Report Date: 4/3/2000

Rodac TSA Plate

Control	Test ID	Test Description	Sample ID	Read Date Time:	Result:
Scheduled Read Date:	Room Description	Alert Limit	Read By:	Ref Doc:	
Ref #	Test Type	Action Limit			
2073	Group 41	Daily Tests	+S05205A		
2073		Site on work surface of laminar flow hood.			
		3/23/00 7:00AM	15		
		E1 Micro Sterility Suite	18		

Rodac TSA Plate

Print #: 0001

Reviewed By: _____

Date: _____

C:\EMS214\reports\ReadingWorksheet.rpt

CSSC Pharmaceuticals

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Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

2069

Survey Control No.

Survey Date: 3/6/00
Survey Shift: 1

Facility: Current Facility
Group: Daily Tests

Product: sqd
Lot #: xdwx

Room ID: 6 RefNo

MicroSterility

Room Description Micro Sterility Suite

Rodac TSA Plate		Sample Date		Test Date		Media Lot		Sample ID		Enter By	
Test ID Ref	Test ID	Test Site Description		Sample By	Test By	Equipment ID	Room Activity	Exception	Room Activity	Enter Date	Enter Date
E1	41	Site on work surface of laminar flow hood.		3/6/00 7:23AM	3/6/00 7:23AM	1234R01	+S05146A		Operational	iradiqan	3/22/00 10:27PM
				TNucci	TNucci	None					
F1	38	Floor site in front of laminar flow hood.		3/6/00 7:05AM	3/6/00 7:05AM	1234R014	+S05143A		Operational	iradiqan	3/22/00 10:27PM
				TNucci	TNucci	None					
F2	39	Floor site in doorway - room entrance.		3/6/00 7:15AM	3/6/00 7:15AM	1234R01	+S05144A		Operational	iradiqan	3/22/00 10:27PM
				TNucci	TNucci	None					
F3	40	Floor site in room corner - general cleanliness assessment.		3/6/00 7:22AM	3/6/00 7:22AM	1234R01	+S05145A		Operational	iradiqan	3/22/00 10:27PM
				TNucci	TNucci	None					
Non Viable Particulate		Sample Date		Test Date		Media Lot		Sample ID		Enter By	
Test ID Ref	Test ID	Test Site Description		Sample By	Test By	Equipment ID	Room Activity	Exception	Room Activity	Enter Date	Enter Date
P1	45	Particulate count taken in room center.		3/6/00 7:15AM	3/6/00 7:15AM	123444	+S05149A	1	Operational	iradiqan	3/22/00 11:15PM
				JRadigan	JRadigan						

Environmental Monitoring System

Report Date: 4/3/2000

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Survey Date: _____ Survey Shift: _____

Room ID: 6

Facility:	Current Facility
Group:	Daily Tests
Product:	sqd
Lot #:	xdwX
12069	3/6/00
1	

RefNo MicroSterility

Touch Plate

Test ID Ref	Test ID	Test Site Description	Touch Plate	Sample Date	Test Date	Media Lot	Exception Employee ID	Entry By Employee ID	Enter Date
				Sample By	Test By	Equipment ID			

42	Touch plate taken within laminar flow hood.	3/6/00	9:25AM	TNucci	1234RU1	GeorgeL	GeorgeL	3/22/00 11:18PM
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42	Touch plate taken within laminar flow hood.	3/6/00	9:26AM	3/6/00	9:26AM	1234R01	+S05147B Operational	RLindsay	iradiqan	3/22/00 11:18PM
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Sample ID	Media Lot	Test Date	Sample Date	STA Plate	Entry BY

44	STA airborne contamination sample taken in room center.	3/6/00 10:25AM	TestQATech	3/6/00 10:25AM	TestQATech	1234R01	None	+S05148A	Operational	iradiqan	3/22/00 11:18PM
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Sample ID	Media Lot	Test Date	Sample Date	Water pH
12345	12345	2023-10-01	2023-09-28	7.2

WF1-000-1	1432	Point Of Use site at WiFi Drop	3/6/00 1:30PM TNUCCI	3/6/00 1:30PM TNUCCI	None None	+S05150A Operational	6.3	iradiqan 3/22/00 11:18PM
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Environmental Monitoring System

Survey Confirmation Worksheet

Report Date: 4/3/2000

2000

Survey Control No.

3/6/00
1

Facility: Current Facility
Group: Daily Tests

Product: sqd
Lot #: xdwx

Room ID: 7 RefNo

MicroGowning

Room Description

Micro Gowning Area

Surface Swab			Test Site Description	Sample Date	Test Date	Media Lot	Sample ID	Room Activity	Exception	Entry By	Enter Date
Test ID	Ref	Test ID	Test Site Description	Sample By	Test By	Equipment ID	Room Activity	Exception	Entry By	Enter Date	
S1	32		Swab sample within sink 1. - tt4hrthth - 222222222222 - Reason #3	3/6/00 TNucci	8:55AM 3/6/00 TNucci	8:55AM 11111111	+S05137A Operational		iradiqan	3/22/00	11:18PM
S2	33		Swab sample within sink 2.	3/6/00 TNucci	8:56AM 3/6/00 TNucci	8:56AM 11111111	+S05138A Operational		iradiqan	3/22/00	11:18PM

Environmental Monitoring System

Report Date: 4/3/2000

Survey Control No. **1234567890** Survey Date: **10/20/2023** Survey Shift: **Day**

Facility: **Current Facility**
Group: **Daily Tests**

2069

Survey Date:
Survey Shift:

Boat ID: 74 Ref ID: Water System

Room Description **Water System**

Product: sqd
Lot #: xdwx

Water Endotoxin EU/ml

Sample ID	Sample Date	Test Date	Media Lot	Result	Entry By
Sample By	Sample By	Test By	Equipment ID	Exception	Enter Date

D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A	3/6/00 8:23AM	3/6/00 11:05AM	Georgel	1234	+S05151A Operational	5.200	iradigan 3/22/00 11:18PM
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room	3/6/00 8:24AM	3/6/00 9:25AM	Georgel	1234	+S05152A Operational	0.530	iradigan 3/22/00 11:18PM

Water pH		Test Site Description		Sample Date	Test Date	Media Lot	Sample ID	Result	Entry By
Test ID Ref	Test ID	Sample By	Test By	Sample Date	Test Date	Equipment ID	Room Activity	Exception	Enter Date
D1PH1	1436	Water pH at Drop 1 in Production Room A	TNucci	3/6/00 10:05AM	3/6/00 10:05AM	12345R	+S05153A	<0.8	jradiagan 3/22/00 11:18PM
						M-002	Operational		

Yes	D3PH3	1438	Water pH at Drop 3 in Production Prep Room	3/6/00 TNucci	10:07AM TNucci	3/6/00 TNucci	10:07AM TNucci	12345R M-002	+S05154A Operational	4.6	iradijan 3/22/00 11:18PM
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Water Conductivity		
Test ID Ref	Test ID	Test Site Description
WFI=003-02	1443	Water Conductivity

Print #: 0002
Reviewed By:
CSSC Pharmaceutical

Environmental Monitoring System

Report Date: 4/3/2000

Survey Control No. 12069

Survey Date: 3/6/00

Survey Shift: 1

Product: sqd
Lot #: xdwx

Facility: EMS Test Facility
Group: Daily Tests

Room ID: 6 RefNo MicroSterility

Room Description Micro Sterility Suite

Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result
			Sample By	Test By	Result By	Room Activity	Exception
			Media Lot	Equipment ID			Enter Date
E1	41	Site on work surface of laminar flow hood.	3/6/00 7:23AM	TNucci 1234R01	3/13/00 7:23AM	VGalliani	+S05146A Operational
F1	38	Floor site in front of laminar flow hood.	3/6/00 7:05AM	TNucci 1234R014	3/13/00 8:00AM	JRadigan	+S05143A Operational
F2	39	Floor site in doorway - room entrance.	3/6/00 7:15AM	TNucci 1234R01	3/13/00 9:00AM	TJoyce	+S05144A Operational
F3	40	Floor site in room corner - general cleanliness assessment.	3/6/00 7:22AM	TNucci 1234R01	3/13/00 9:05AM	TJoyce	+S05145A Operational

Environmental Monitoring System

Report Date: 4/3/2000

Survey Control No. _____
Survey Date: _____
Survey Shift: _____

Facility: EMS Test Facility
Group: Daily Tests

Product: sqd
Lot #: xcdwx

Room ID: 6 RefNo: MicroSterility

Non Viable Particulate

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Test ID	Test Site Description
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Result By Room Activity Exception Enter Date

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Sample Bv

113

Site Description

Test ID

100

Media Lot	Equipment ID	Media Lot	Equipment ID
45	Particulate count taken in room center.	3/6/00 7:15AM JRadigan None	3/6/00 7:15AM JRadigan 123444

Test ID	Test Site Description
Touch Plate	
Test ID	Test Site Description
Test ID	Test Site Description

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Instrument	Location	Sample ID	Sample Name	Sample Type	Sample Description	Sample Date	Sample Time	Sample Operator	Sample Status	Instrument	Location	Sample ID	Sample Name	Sample Type	Sample Description	Sample Date	Sample Time	Sample Operator					
RLindsay	42	Touch plate taken within laminar flow hood.	TNucci	3/6/00	9:25AM	3/6/00	9:25AM	JRadigan	3/13/00	10:00AM	+S05147A	2	Georgel	1234R01	Touch plate taken within laminar flow hood.	TNucci	3/6/00	9:26AM	3/13/00	10:00AM	+S05147B	2	Georgel
RLindsay	42	Touch plate taken within laminar flow hood.	TNucci	3/6/00	9:26AM	3/6/00	9:26AM	RLindsay	3/13/00	10:00AM	Operational	RLindsay	1234R01	Touch plate taken within laminar flow hood.	TNucci	3/6/00	9:26AM	3/13/00	10:00AM	Operational	RLindsay		

Test ID Ref	Test ID	STA Plate	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result	Entry By
				Sample BV	Test BV	Result BV	Room Activity	Exception	Enter Date
1	44	1234R01	STA airborne contamination sample taken in room center.	3/6/00 10:25AM	3/6/00 10:25AM	3/11/00 11:00AM	+S05148A	3	iradiqan
		TestQATech	TestQATech				Operational		3/22/20 11:18PM

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

Survey Control No. **2069**

Survey Date: 3/6/00

Survey Shift: 1

Room ID: 6 RefNo MicroSterility

Facility: EMS Test Facility
Group: Daily Tests

Product: sqd
Lot #: xdwx

Room Description
Micro Sterility Suite

Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Result	Enter EV
			Sample By	Test By	Result By	Room Activit	Exception	Enter Date
			Media Lot	Equipment ID				
WFI-000-1	1432	Point Of Use site at WFI Drop	3/6/00 1:30PM	TNucci	3/6/00 1:30PM	+S05150A	6.3	iradican
			None	None	TJoyce	Operational		3/22/00 11:18PM

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2069

Survey Control No.

3/6/00

Facility: EMS Test Facility

Group: Daily Tests

Product: sqd
Lot #: xdwx

Room ID: 7 RefNo MicroGowning

Room Description

Micro Gowning Area

Surface Swab			Test ID Ref	Test ID	Test Site Description	Sample Date	Test Date	Test By	Equipment ID	Result Date	Room Activity	Sample ID	Result	Exception	Enter EV	Enter Date
						Sample By	Result By									
						Media Lot										
						3/6/00	8:55AM	TNucci	3/6/00	8:55AM	RWatson	+S05137A	9		iradigan	3/22/00 11:18PM
						1111111										
- tt4hrthrth - 222222222222 - Reason #3																
						3/6/00	8:56AM	TNucci	3/13/00	8:56AM	RLindsay	+S05138A	2		iradigan	3/22/00 11:18PM
						1111111										

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2069

Survey Contol No.

3/6/00
1

Product:
sqd
Lot #: xdwx

Facility: EMS Test Facility
Group: Daily Tests

Survey Date:
Survey Shift:
Room ID: 74

RefNo

Water System

Room Description Water System

Water Endotoxin EU/ml		Test Site Description		Sample Date		Test Date		Result Date		Sample ID		Result	
Test ID	Ref	Test ID	Test Site Description	Sample By	Sample ID	Test By	Test ID	Result By	Equipment ID	Room Activity	Exception	Entry By	Enter Date
D1LAL1	1433	Water Endotoxin at Drop 1 in Production Room A		3/6/00 8:23AM	TNucci	3/6/00 11:05AM	GeorgeL	T.Joyce	+S05151A Operational	5.200	iradigan	3/22/00 11:18PM	
D3LAL3	1435	Water Endotoxin test at Drop 3 in Production Prep Room		3/6/00 8:24AM	TNucci	3/6/00 9:25AM	GeorgeL	T.Joyce	+S05152A Operational	0.530	iradigan	3/22/00 11:18PM	
D1PH1	1436	Water pH at Drop 1 in Production Room A		3/6/00 10:05AM	TNucci	3/6/00 10:05AM	T.Nucci	T.Joyce	+S05153A Operational	<0.8	iradigan	3/22/00 11:18PM	
D3PH3	1438	Water pH at Drop 3 in Production Prep Room		3/6/00 10:07AM	TNucci	3/6/00 10:07AM	T.Nucci	T.Joyce	+S05154A Operational	4.6	iradigan	3/22/00 11:18PM	
Yes													

Environmental Monitoring System

Survey Results

Report Date: 4/3/2000

2069

Survey Control No.
Survey Date:
Survey Shift:

Product:
Lot #:
sqd
xdwx

Room ID: 74

RefNo
Room Description
Water System

Facility: EMS Test Facility
Group: Daily Tests

Water Conductivity			Test Site Description	Sample Date	Test Date	Result Date	Sample ID	Room Activity	Result	Entry By	Enter Date
Test ID	Ref	Test ID	Test Site Description	Sample By	Test By	Result By	Equipment ID	Exception	Exception	Exception	Exception
WFI=003-02	1443		Water Conductivity	3/6/00	10:45AM	3/6/00	10:45AM	+S05155A	>4.5	iradiqan	3/22/00 11:18PM
				TNucci	TNucci		Operational	M-002			

NQ Reason

Microbial Over Action Limits Investigation

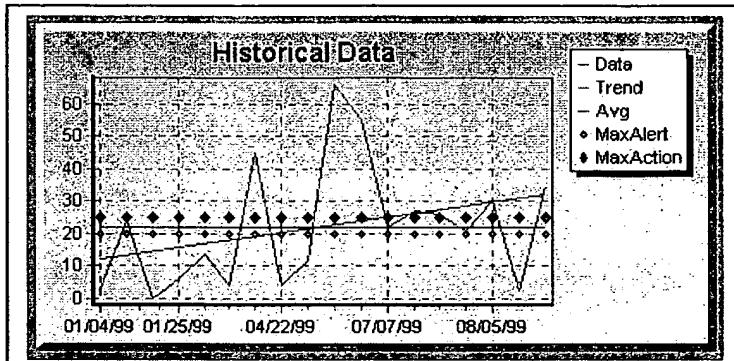
Control No. 2047

Sample Date 09/02/1999 Product name P-WFI20ml-002 Lot 12345-SD-55
Room: 6 Production Fill Line #6
Sample Site 38 - Floor site in front of laminar flow hood.
Result 35 Alert Level 20 Action Level 25

Trending information.

Dates trended: From 10/12/1998 To 10/12/1999

List dates of any excursions for this site and the results



Dates subsequent samples and the results / / / / / / / /

Product Sterility Test Result: Pass Fail
Endotoxin results: Pass Fail
(if a gram negative isolate only):

Microbial Characterization potential source of organism

1. VITEK Id Number: _____ VITEK characterization: _____

2. API 20 E Lot No. _____ Exp. Date: _____ API 20E Id No. _____
API 20 E Characterization

3. API 20NE Lot No. _____ Exp. Date: _____ API 20NE Id No. _____
API 20NE Characterization

3. API 20NE Lot No. _____ Exp. Date: _____ API 20NE Id No. _____

3. API 20NE Lot No. _____ Exp. Date: _____ API 20NE Id No. _____
API 20NE Characterization

Suspected Source of organism: _____

List any calibration or maintenance that has been done in the area that may have affected the sample.

Digitized by srujanika@gmail.com

Comments _____

Investigation Conducted by _____ Date _____

Reviewed by _____ Date _____

Microbial Monitoring Advers Trend Report

To: _____

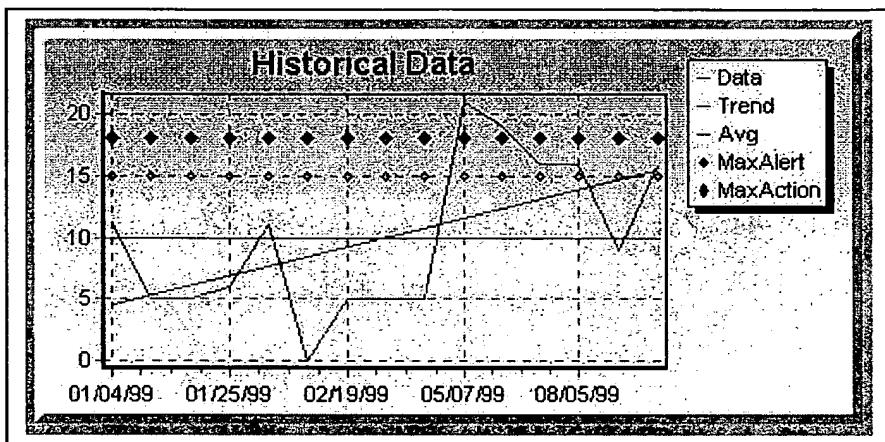
From: Microbiology Supervisor

The following site has developed an adverse trend and needs immediate attention.

Sample Date 09/07/1999
Room: 6
Sample Site 41 - Site on work surface of laminar flow hood.
Result 16 Alert Level 15 Action Level 18

Trending information.

Dates trended: From 10/14/1998 To 10/14/1999



This section to be filled out by the manager or supervisor responsible for the area

Possible cause for the trend

Corrective action and date implemented

Signature _____ Title _____ Date _____

This Section to be filled out by Microbiology Supervisor or designee

Results of samplings since the corrective action

Is the corrective action effective based upon the results? _____ Yes _____ No

Signature _____ Title _____ Date _____

Objectionable Microbial Organism Notification Report

To: _____

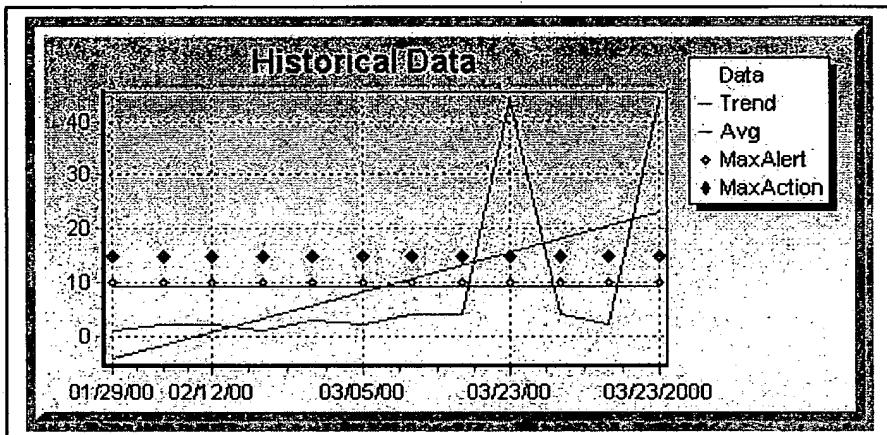
From: Environmental Monitoring System

During routine organism identification monitoring, the following objectionable organism was detected. ***Bacillus cereus***

Sample Date 03/23/2000
Survey Number: 1050 Sample ID: +S07354A
Room: 5 - Micro Lab2 A174
Sample Site 4 - Floor Between hood #1 and hood #2. Sample approx 2 feet in front.
Result 44 Alert Level 10 Action Level 15

Trending information.

Dates trended: From 07/28/1999 To 07/28/2000



This section to be filled out by the manager or supervisor responsible for the area

Possible cause for the appearance of this organism _____

Corrective action and date implemented

Signature _____ Title _____ Date _____

This Section to be filled out by Microbiology Supervisor or designee

Results of samplings since the corrective action _____

Is the corrective action effective based upon the results? _____ Yes _____ No

Signature _____ Title _____ Date _____

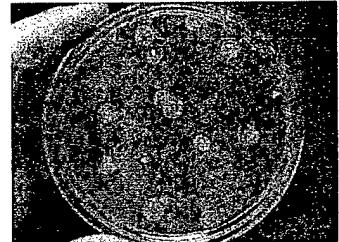
Environmental Monitoring System

Report Date 10/20/99

Out of Limits Deviation Report

Control Number 2015 Close Status Yes
 Survey Number 1046
 Sample ID 0/09992

Test Date 5/7/99 7:57:00AM Shift 2 Group Weekly Assesment
 Test ID 40 Room Desc Micro Sterility Suite
 Test User Ref R-002-B
 Test Desc Floor site in room corner - general cleanliness assessment.
 Test Type Rodac Plates TSA
 Read Date 5/14/99 5:25:00AM Read By JRadigan
 Reading 33.00 AlertLimit 0.00 25.00 Action Limit 0.00 30.00



Investigation Activities		Investigation Narrative	
Check Maint Log		Yes	
Check Cleaning Log		Yes	
Review Batch Record Data		Yes	
Verify Training Records		Yes	
Review Other OOL Cond		Yes	
Check Utilities		Yes	
Verify Calibration Docs		Yes	
Review Lab Docs		Yes	
Review Test Procedures		Yes	
Other		No	

Organism Identifications

Obs	Source	Report ID	Equipment ID	ID Date	ID By	
1	Vitek	10424	1224-NF	5/18/99 12:00:00AM	JRadigan	
	Gram Stain	Microscopic	Organism Type	Species		
	Neg	rod	Bacteria	Bacillus subtilis		
Obs	Source	Report ID	Equipment ID	ID Date	ID By	
2	Vitek	12377	1224-NF	5/18/99 12:00:00AM	JRadigan	
	Gram Stain	Microscopic	Organism Type	Species		
	Pos	rod	Bacteria	Bacillus stearothermophilus		

Corrective Action

Gowning and production procedures were reviewed with all production technicians. Cleaning procedures were also reviewed with cleaning crew.

Conclusions

No single cause could be determined as review of documents and procedures did not identify any deviations from normal routine. It is concluded that the cause is most probably due to technician contamination. All technicians involved in production on this date were counselled and aseptic gowning and operational procedures were reviewed. Subsequent testing demonstrated return to normal levels.

Close Date 9/13/99 8:41:48AM

Close By jradigan

Sample Database Listing

Environmental Monitoring System

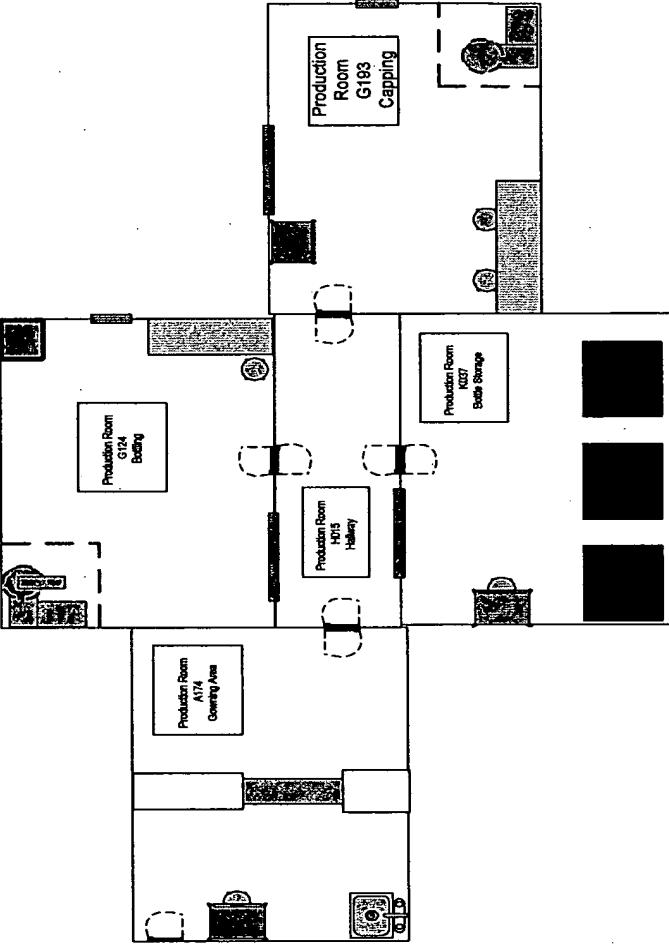
Report Date: 10/20/99

Facility ID	Facility Name	Active Status	Last Maint Date	Last Maint By	Req Equip	Req Media Lot	Assign Samp ID	Review Date	Review Freq
2	EMS Test Facility	Yes	10/2/99	jradigan	Yes	Yes	Yes	5/1/99	Monthly
3	Test QA/QC Facility	No	8/25/99	jradigan	No	No	No	6/1/99	Monthly
4	Jordan Validation	Yes	8/25/99	jradigan	Yes	Yes	Yes	6/1/99	Annually
5	Jordan Pharmaceuticals	Yes	8/23/99	jradigan	Yes	Yes	Yes	6/1/99	Annually
8	Test Jordan Facility	Yes	9/8/99	jradigan	No	No	Yes	6/1/99	Quarterly
9	New Water Facility	Yes	9/28/99	jradigan	Yes	Yes	Yes		
10	EMS Test Facility 2	Yes	10/14/99	jradigan	Yes	Yes	Yes		Annually

Environmental Monitoring System

Report Date: 10/20/99

Facility Layout

Facility ID	Facility Name	Last Maint Date	Last Maint By	Review Frequency	Last Review Date
2 EMS Test Facility					
Active	Status: Yes	10/2/99	jradigan	Monthly	5/1/99
Auto Sample ID No.	Yes				
Require Media Lot	Yes				
Require Equipment ID	Yes				
					

Environmental Monitoring System

Report Date 10/20/99

Facility ID 2 Name EMS Test Facility

Room ID 4 Room Ref No A174

Room Description



Room X 0 Room Y 0

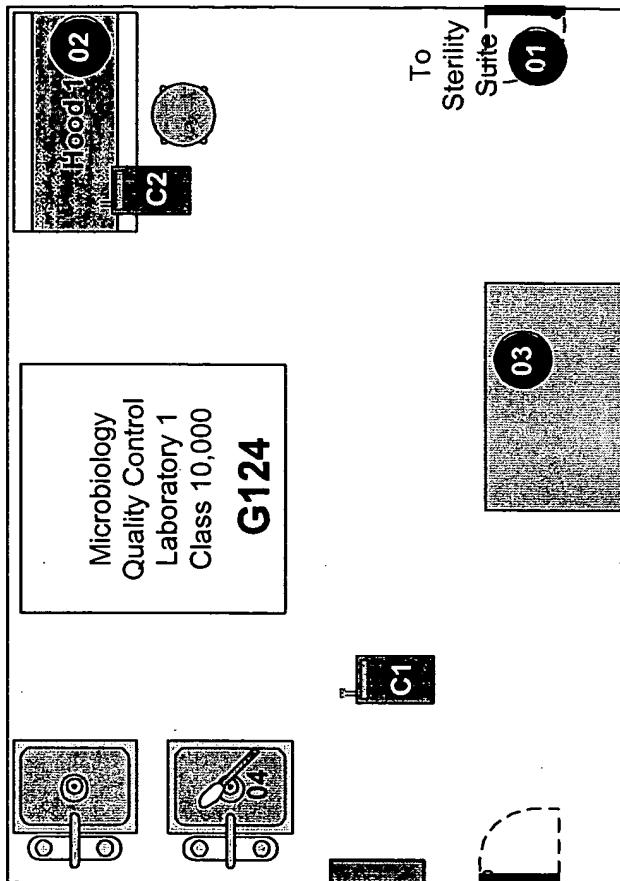
Room Classification Class 10,000

Production Area Classification

Not Classified

Last Maint Date 1999/10/18 09:38:12.00

Last Maint By jradigan



Environmental Monitoring System

Report Date 10/20/99

Room ID 5 Room Ref No MicroLab2 A1

Room Description

MicroLab2 A174

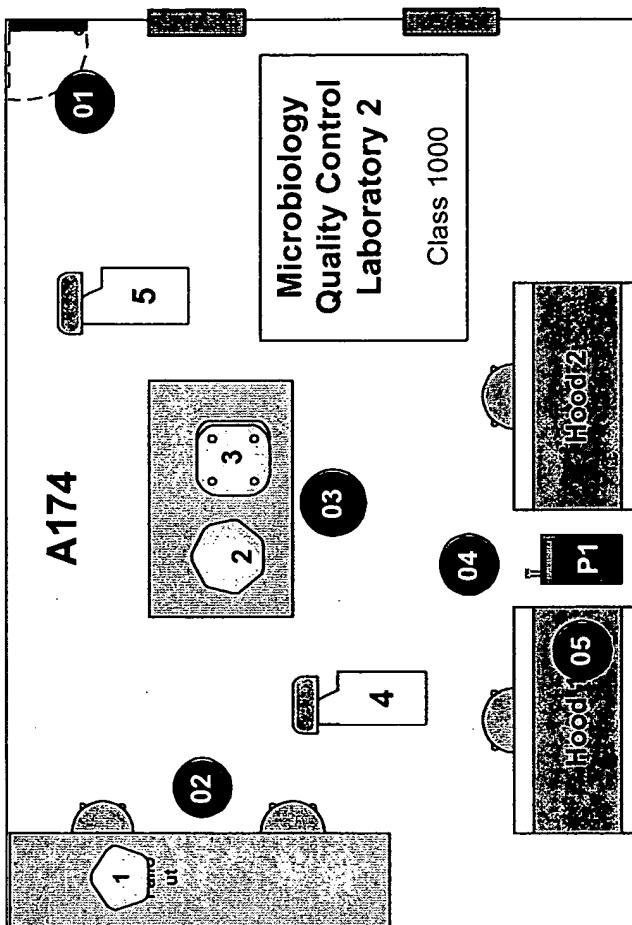
Room X 0 Room Y 0

Room Classification Class 10,000

Production Area Classification Class 100

Last Maint Date 1999/09/30 04:28:35.00

Last Maint By jradigan



Environmental Monitoring System

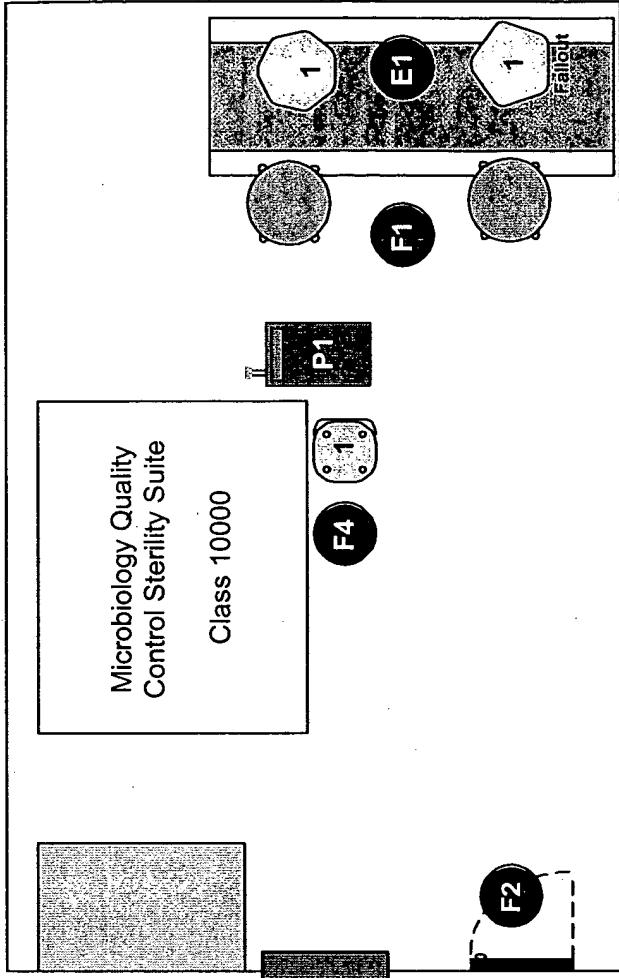
Report Date 10/20/99

Room ID 6 Room Ref No MicroSterility

Room Description

MicroSterility Suite

Room X 0 Room Y 0
Room Classification Class 100,000 Class 100,000 Class 100
Production Area Classification Class 100
Last Maint Date 1999/08/26 15:45:46.00
Last Maint By jradigan



Environmental Monitoring System

Site Description Listing

Report Date:

Site ID	Site Description
1	Wall
2	Floor
3	Glove
4	Garment
5	Production Surface
6	Work Surface
7	Critical Surface
8	Counter
9	Door
10	Water
11	Pressure
12	Sink
13	Room Air
14	HEPA Curtains
15	Tools
16	Ceiling
17	General assessment site.
18	Pass-through
19	Non-Viable Particulate
20	Equipment

Environmental Monitoring System

Report Date: 10/20/99

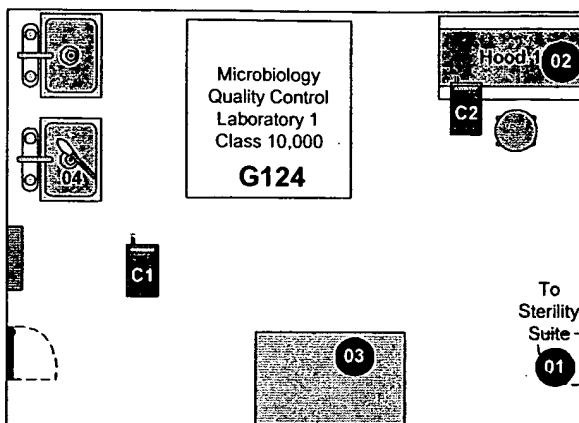
Room ID 4 Room Ref A174

Room Description
Micro Lab 1

Classification
Not Classified

Survey Site Listing By Room

Facility EMS Test Facility



Rodac/ISA Plate

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
13	Floor	site in doorway - room entrance.
F1	Viable	Floor
Test Memo		
14	Floor	site in front of laminar flow hood.
F2	Viable	Floor
Test Memo		
15	Floor	site in doorway - to sterility suite.
F3	Viable	Floor
Test Memo		
16	Floor	site in front of sinks.
F4	Viable	Floor
Test Memo		
17	Floor	site in center of room.
F5	Viable	Floor
Test Memo		
18	Critical Surface	site on work surface of laminar flow hood.
E1	Viable	Critical Surface
Test Memo		

RODAC.ICO

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	25.000
	False	0.000	30.000
	False	0.000	25.000
	False	0.000	30.000
	True	0.000	25.000
	False	0.000	30.000
	True	0.000	30.000
	False	0.000	35.000
	True	0.000	25.000
	False	0.000	30.000
	True	0.000	15.000
	False	0.000	20.000

RCS/Air Sample

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
22	Touch plate taken on work surface.	
ZZ1	Viable	Glove
Test Memo		

RCS.ico

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	22.000
	False	0.000	30.000

Non Viable Particulate

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
24	Particulate count taken in room center.	
P1	NonViable	Counter
Test Memo		

Particle.ico

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	3.000
	False	0.000	7.000

Environmental Monitoring System

Survey Site Listing By Room

Report Date: 10/20/99

Facility EMS Test Facility

Fallout Plate

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
21		Fallout plate within laminar flow hood.
1	Viable	Critical Surface
Test Memo		

SAS.ico

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	20.000
	False	0.000	25.000

STA Plate

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
23		Airborne contamination count taken in center of room.
1	Viable	Counter
Test Memo		

STA.ico

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	30.000
	False	0.000	40.000

Surface Swab

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
19		Swab sample within sink 1.
S1	Viable	Work Surface
Test Memo		
20		Swab sample within sink 2.
S2	Viable	Work Surface
Test Memo		

Swab.ico

Test SOP	One Side	Min Alert Limit	Max Alert Limit
	Lot Specific	Min Action Limit	Max Action Limit
	True	0.000	40.000
	False	0.000	50.000
	True	0.000	40.000
	False	0.000	50.000

Environmental Monitoring System

Survey Site Listing By Room

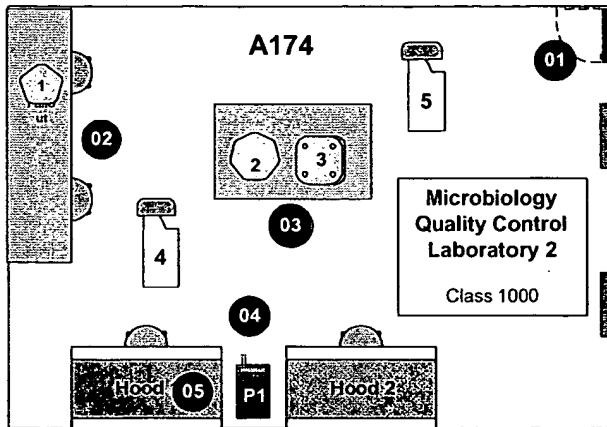
Report Date: 10/20/99

Room ID 5 Room Ref MicroLab2 A174

Room Description
Micro Lab2 A174

Classification
Class 10,000

Facility EMS Test Facility



Rodac/TSIA Plate

RODAC.ICO

Test ID	Test Description	Site Desc	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat			Lot Specific	Min Action Limit	Max Action Limit
3	Floor between workstations approx 2 feet in front of work table.			True	0.000	4.000
02	Viable	Floor	iiii	False	0.000	6.000
Test Memo						
4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.			True	0.000	10.000
04	Viable	Floor		False	0.000	15.000
Test Memo						
5	Floor in center of room.			False	0.000	13.000
03	Viable	Floor		False	0.000	15.000
Test Memo						
6	Floor in doorway / room entrance			True	0.000	13.000
01	Viable	Floor		False	0.000	15.000
Test Memo						
7	Floor in room corner - assess general room cleanliness.			True	0.000	20.000
F5	Viable	Floor		False	0.000	30.000
Test Memo						
8	Site on work surface of laminar hood 1.			True	0.000	12.000
05	Viable	Critical Surface		False	0.000	15.000
Test Memo						
9	Site on work surface of laminar hood 2.			False	0.000	12.000
E2	Viable	Critical Surface		False	0.000	15.000
Test Memo						

Non Viable Particulate

Particle.ico

Test ID	Test Description	Site Desc	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat			Lot Specific	Min Action Limit	Max Action Limit
12	Particulate count taken between laminar flow hoods.			True	0.000	3.000
P1	NonViable	Counter		False	0.000	7.000
Test Memo						

Touch Plate

Touch.ico

Test ID	Test Description	Site Desc	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat			Lot Specific	Min Action Limit	Max Action Limit

Environmental Monitoring System

Survey Site Listing By Room

Report Date: 10/20/99

10 Personnel touch plate.
T1 Viable Glove
Test Memo tytytryty

Facility EMS Test Facility

True	0.000	15.000
True	0.000	20.000

STAPlate

STA.ico

Test ID	Test Description	
Test Ref	Test Cat	Site Desc
11	Airborne contamination	STA plate in center of room.
S1	Viable	Counter
Test Memo		

Test SOP	One Side	Min Alert Limit	Max Alert Limit
Lot Specific	Min Action Limit	Max Action Limit	
	True	0.000	20.000
	False	0.000	30.000

Environmental Monitoring System

Survey Site Listing By Room

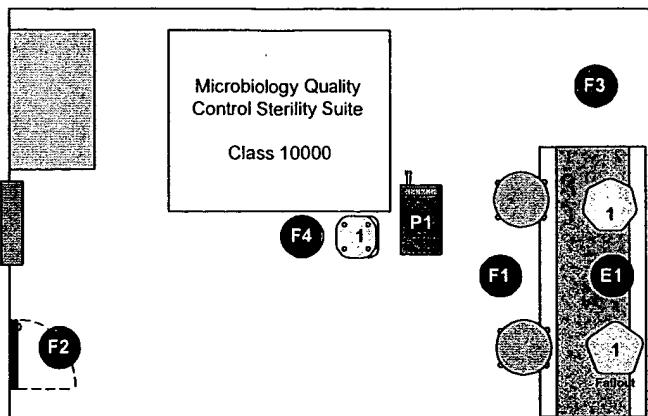
Report Date: 10/20/99

Facility EMS Test Facility

Room ID 6
Room Ref MicroSterility

Room Description
Micro Sterility Suite

Classification
Not Classified



Rodac.TSA Plate

RODAC.ICO

Test ID	Test Description	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Lot Specific	Min Action Limit	Max Action Limit
38	Floor site in front of laminar flow hood.		True	0.000	20.000
F1	Viable	Floor	False	0.000	25.000
Test Memo					
39	Floor site in doorway - room entrance.		True	0.000	25.000
F2	Viable	Floor	False	0.000	30.000
Test Memo					
40	Floor site in room corner - general cleanliness assessment.		True	0.000	25.000
F3	Viable	Floor	False	0.000	30.000
Test Memo					
41	Site on work surface of laminar flow hood.		True	0.000	15.000
E1	Viable	Critical Surface	False	0.000	18.000
Test Memo					

Non Viable Particulate

Particle.ICO

Test ID	Test Description	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Lot Specific	Min Action Limit	Max Action Limit
45	Particulate count taken in room center.		True	0.000	2.000
P1	NonViable	Counter	False	0.000	5.000
Test Memo					

Touch Plate

Touch.ICO

Test ID	Test Description	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Lot Specific	Min Action Limit	Max Action Limit
42	Touch plate taken within laminar flow hood.		True	0.000	15.000
1	Viable	Glove	False	0.000	18.000
Test Memo					

Fallout Plate

SAS.ICO

Test ID	Test Description	Test SOP	One Side	Min Alert Limit	Max Alert Limit
Test Ref	Test Cat	Site Desc	Lot Specific	Min Action Limit	Max Action Limit

Environmental Monitoring System

Survey Site Listing By Room

Report Date: 10/20/99

43. Fallout plate taken within laminar flow hood.
1 Viable Critical Surface

Test Memo

Facility EMS Test Facility

True	0.000	10.000
False	0.000	15.000

STA Plate

STA.ico

Test ID	Test Description	Test Ref	Test Cat	Site Desc	Test SOP	One Side	Min Alert Limit	Max Alert Limit
						Lot Specific	Min Action Limit	Max Action Limit
44	STA airborne contamination sample taken in room center.	1	Viable	Counter		True	0.000	20.000
						False	0.000	25.000

Test Memo

Water pH

ChemGen.ico

Test ID	Test Description	Test Ref	Test Cat	Site Desc	Test SOP	One Side	Min Alert Limit	Max Alert Limit
						Lot Specific	Min Action Limit	Max Action Limit
1432	Point Of Use site at WFI Drop	WFI-000-1	Water	Water	WFI -122222	False	5.500	7.200
						False	6.000	7.900

Test Memo

Environmental Monitoring System

Report Date: 10/20/99

Test Survey Site Identification

Facility: EMS Test Facility 2

Room ID 99 Room Description Room G124

Test ID	Test User Ref	Test ID Description	Classification	Test Type	Test Type	Classification	Test Type	Classification	Test Type	Classification
1428 01		Floor Rodac	Class 10,000	Rodac TSA Plate	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000
Test SOP	JJ123456			Site Desc	Site Desc		Site Desc		Site Desc	
Lot Specific	No			Category	Category		Category		Category	
Maint Date	10/18/99	Maint By	jradigan	One Side	One Side		One Side		One Side	
Test Memo				Yes	Yes		Yes		Yes	
1429 02		Counter Rodac	Class 10,000	Rodac TSA Plate	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000
Test SOP	JJ666688			Site Desc	Site Desc		Site Desc		Site Desc	
Lot Specific	No			Category	Category		Category		Category	
Maint Date	9/30/99	Maint By	jradigan	One Side	One Side		One Side		One Side	
Test Memo				Yes	Yes		Yes		Yes	
1430 03		Work Surface	Class 10,000	Rodac TSA Plate	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000
Test SOP	JJ890777			Site Desc	Site Desc		Site Desc		Site Desc	
Lot Specific	No			Category	Category		Category		Category	
Maint Date	9/30/99	Maint By	jradigan	One Side	One Side		One Side		One Side	
Test Memo				Yes	Yes		Yes		Yes	
1431 04		Sink Swab	Class 10,000	Rodac TSA Plate	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000	Rodac TSA Plate	Class 10,000
Test SOP	JJ3456-R5			Site Desc	Site Desc		Site Desc		Site Desc	
Lot Specific	No			Category	Category		Category		Category	
Maint Date	9/30/99	Maint By	jradigan	One Side	One Side		One Side		One Side	
Test Memo				Yes	Yes		Yes		Yes	

Environmental Monitoring System

Test Type Listing

ID	Description	Inc Temp	Inc Hours	TNTC Val	Last Maint By	Test Code	Desc
	Test SOP	Test Media			Last Maint Date	Icon Fil	Nam
1	Rodac TSA Plate	33-37	168	100	jradigan		Viable
		TSA			10/19/99 5:53:08AM	RODAC.ICO	
2	Rodac Plates RB	50-55	168	300	jradigan		Viable
		Rose Bengal			10/19/99 5:55:19AM	RCS.ico	
3	RCS Air Sample	33-37	120	300	jradigan		Viable
		TSA			10/19/99 5:55:24AM	RCS.ico	
4	RCS Air Sample RB	50-55	120	300	jradigan		Viable
		Rose Bengal			10/19/99 5:55:30AM	RCS.ico	
5	Non Viable Particulate	None	0	0	jradigan		NonViable
		None			8/19/99 5:41:45AM	Particle.ico	
7	Water TOC	33-37	120	300	jradigan		Water
		TSB			8/19/99 5:41:50AM	TOC.ico	
8	Touch Plate	33-37	168	300	jradigan		Viable
		TSA			8/19/99 5:41:56AM	Touch.ico	
9	Settling Plate	33-37	168	300	jradigan		Viable
	ddddd	TSA			8/19/99 5:42:02AM	Settle.ico	
10	Fallout Plate	33-37	120	300	jradigan		Viable
		TSA			8/19/99 5:42:07AM	SAS.ico	
11	STA Plate	33-37	120	300	jradigan		Viable
		TSA			8/19/99 5:42:12AM	STA.ico	
12	Surface Swab	33-37	168	300	jradigan		Viable
		TSA			10/5/99 11:30:44AM	Swab.ico	
14	SAS Air Sample	33-37 C	168	300	jradigan		Viable
		TSA			8/19/99 5:42:22AM	SAS.ico	
15	Garment Sample	33-37	120	300	jradigan		Viable
		TSA			8/19/99 5:42:26AM	Gown.ico	

Environmental Monitoring System

Test Type Listing

10/20/99

ID	Description	IncTemp	Inc Hours	TNTC Val	Last Maint By	Test Code Desc
16	Test SOP Water Endotoxin	Test Media 36-38	4	5	jradigan	Icon Fil Nam Water
		None			8/19/99 5:42:31AM	LAL.ico
17	Water Microbial	33-37	120	300	jradigan	Water
		TSA			8/19/99 5:42:34AM	WATER.ICO
18	Water pH	None	0	14	jradigan	Water
		None			8/19/99 5:42:39AM	ChemGen.ico
19	Water Metals	None	0	0	jradigan	Water
		None			8/19/99 5:42:45AM	WATER.ICO
20	Water Conductivity	None	0	5000	jradigan	Water
		None			8/19/99 5:42:49AM	ChemGen.ico
21	Water Coliform	None	0	300	jradigan	Water
		None			9/16/99 8:45:19AM	MicroGen.ico
22	test	88	168	30	jradigan	Viable
		jmj			8/19/99 5:42:54AM	Rodac2.ico

Environmental Monitoring System

Report Date: 10/20/99

Survey Groups

Facility ID:	2	Facility Name:	EMS Test Facility	Frequency	Lot Specific	Group Active	Random Pick	Picks Per Survey	Last Maint Date	Last Maint By
Group ID	Group Description									
2	Weekly Tests		Weekly	No	No	No	No	5	8/31/99	jradigan
3	Daily Tests		Daily	Yes	No	No	No	10	8/26/99	jradigan
19	Production Daily		Daily	Yes	Yes	Yes	No	10	9/17/99	jradigan

Environmental Monitoring System

Report Date: 10/20/99

Group Assignments

Facility: EMS Test Facility

Daily Tests			Group ID	3
Micro Gowning Area			MicroGowning	
Non Viable Particulate				
	Test ID	Test ID User Ref	Test Site Description	
	36	P1	Particulate count taken in center of wash area.	
	37	P2	Particulate count taken in center of clean area.	
RCS Air Sample				
	Test ID	Test ID User Ref	Test Site Description	
	34	R1	RCS airborne contamination sample taken in center of wash area.	
	35	R2	RCS airborne contamination sample taken in center of clean area.	
Surface Swab				
	Test ID	Test ID User Ref	Test Site Description	
	32	S1	Swab sample within sink 1.	
	33	S2	Swab sample within sink 2.	
Micro Sterility Suite			MicroSterility	
Non Viable Particulate				
	Test ID	Test ID User Ref	Test Site Description	
	45	P1	Particulate count taken in room center.	
Rodac TSA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	38	F1	Floor site in front of laminar flow hood.	
	39	F2	Floor site in doorway - room entrance.	
	40	F3	Floor site in room corner - general cleanliness assessment.	
	41	E1	Site on work surface of laminar flow hood.	
STA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	44	1	STA airborne contamination sample taken in room center.	
Touch Plate				
	Test ID	Test ID User Ref	Test Site Description	
	42	1	Touch plate taken within laminar flow hood.	
Water pH				
	Test ID	Test ID User Ref	Test Site Description	
	1432	WFI-000-1	Point Of Use site at WFI Drop	

Weekly Tests			Group ID	2
Micro Gowning Area			MicroGowning	

Non Viable Particulate	Test ID	Test ID User Ref	Test Site Description
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Environmental Monitoring System

Group Assignments

Report Date: 10/20/99

Facility: EMS Test Facility

Weekly Tests	Group ID	2	
Micro Gowning Area			
Non Viable Particulate		MicroGowning	
	Test ID	Test ID User Ref	Test Site Description
	36	P1	Particulate count taken in center of wash area.
	37	P2	Particulate count taken in center of clean area.
RCS Air Sample		Test Site Description	
	Test ID	Test ID User Ref	
	34	R1	RCS airborne contamination sample taken in center of wash area.
	35	R2	RCS airborne contamination sample taken in center of clean area.
Rodac TSA Plate		Test Site Description	
	Test ID	Test ID User Ref	
	25	F1	Floor site in doorway - room entrance.
	26	F2	Floor site on wash side of bench designating class transition area.
	27	F3	Floor site on clean side of bench designating class transition area.
	28	F4	Floor site in doorway leading to controlled area.
	29	W1	Wall site near doorway - room entrance.
	30	W2	Wall site on near wall - general cleanliness assessment.
	31	W3	Wall site near door leading to controlled area.
Surface Swab		Test Site Description	
	Test ID	Test ID User Ref	
	32	S1	Swab sample within sink 1.
	33	S2	Swab sample within sink 2.
Micro Lab 1		A174	
Fallout Plate		Test Site Description	
	Test ID	Test ID User Ref	
	21	1	Fallout plate within laminar flow hood.
Non Viable Particulate		Test Site Description	
	Test ID	Test ID User Ref	
	24	P1	Particulate count taken in room center.
RCS Air Sample		Test Site Description	
	Test ID	Test ID User Ref	
	22	ZZ1	Touch plate taken on work surface.
Rodac TSA Plate		Test Site Description	
	Test ID	Test ID User Ref	
	13	F1	Floor site in doorway - room entrance.
	14	F2	Floor site in front of laminar flow hood.
	15	F3	Floor site in doorway - to sterility suite.
	16	F4	Floor site in front of sinks.
	17	F5	Floor site in center of room.

Environmental Monitoring System

Group Assignments

Report Date: 10/20/99

Facility: EMS Test Facility

Weekly Tests			Group ID	2
Micro Lab 1			A174	
Rodac TSA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	18	E1	Site on work surface of laminar flow hood.	
STA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	23	1	Airborne contamination count taken in center of room.	
Surface Swab				
	Test ID	Test ID User Ref	Test Site Description	
	19	S1	Swab sample within sink 1.	
	20	S2	Swab sample within sink 2.	
Micro Lab2 A174			MicroLab2 A174	
Non Viable Particulate				
	Test ID	Test ID User Ref	Test Site Description	
	12	P1	Particulate count taken between laminar flow hoods.	
Rodac TSA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	3	02	Floor between workstations approx 2 feet in front of work table.	
	4	04	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.	
	5	03	Floor in center of room.	
	6	01	Floor in doorway / room entrance	
	8	05	Site on work surface of laminar hood 1.	
	9	E2	Site on work surface of laminar hood 2.	
STA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	11	S1	Airborne contamination STA plate in center of room.	
Touch Plate				
	Test ID	Test ID User Ref	Test Site Description	
	10	T1	Personnel touch plate.	
Micro Sterility Suite			MicroSterility	
Non Viable Particulate				
	Test ID	Test ID User Ref	Test Site Description	
	45	P1	Particulate count taken in room center.	
Rodac TSA Plate				
	Test ID	Test ID User Ref	Test Site Description	
	38	F1	Floor site in front of laminar flow hood.	
	39	F2	Floor site in doorway - room entrance.	
	40	F3	Floor site in room corner - general cleanliness assessment.	

Environmental Monitoring System

Group Assignments

Report Date: 10/20/99

Facility: EMS Test Facility

Weekly Tests			Group ID	2
Micro Sterility Suite			MicroSterility	
Rodac TSA Plate			Test Site Description	
	Test ID	Test ID User Ref	Site on work surface of laminar flow hood.	
	41	E1		
STA Plate			Test Site Description	
	Test ID	Test ID User Ref	STA airborne contamination sample taken in room center.	
	44	1		
Touch Plate			Test Site Description	
	Test ID	Test ID User Ref	Touch plate taken within laminar flow hood.	
	42	1		
Production Room 100 Hallway			Prod100	
Non Viable Particulate			Test Site Description	
	Test ID	Test ID User Ref	Particulate count in center of room.	
	102	P1		
RCS Air Sample			Test Site Description	
	Test ID	Test ID User Ref	RCS airborne contamination sample in center of room.	
	101	R1		
Rodac TSA Plate			Test Site Description	
	Test ID	Test ID User Ref	Floor site near doorway to room 101.	
	93	F1	Floor site near doorway to room 103.	
	94	F2	Floor site near doorway to room 102.	
	95	F3	Floor site near doorway to room 104.	
	96	F4	Wall site near doorway to room 101.	
	97	W1	Wall site near doorway to room 103.	
	98	W2	Wall site near doorway to room 102.	
	99	W3	Wall site near doorway to room 104.	
	100	W4		
Production Room 101 Gowning Area			Prod101	
Non Viable Particulate			Test Site Description	
	Test ID	Test ID User Ref	Particulate count in center of wash area.	
	91	P1		
	92	P2	Particulate count in center of clean area.	
RCS Air Sample			Test Site Description	
	Test ID	Test ID User Ref	RCS airborne contamination sample in center of wash area.	
	89	R1	RCS airborne contamination sample in center of clean area.	
	90	R2		
Rodac TSA Plate			Test Site Description	
	Test ID	Test ID User Ref		

Environmental Monitoring System

Group Assignments

Report Date: 10/20/99

Facility: EMS Test Facility

Weekly Tests	Group ID	2	
Production Room 101 Gowning Area		Prod101	
Rodac TSA Plate			
	Test ID	Test ID User Ref	Test Site Description
	80	F1	Floor site in doorway - room entrance.
	81	F2	Floor site in wash area near bench designating class transition area.
	82	F3	Floor site on clean side near bench designating class transition area.
	83	F4	Floor site near door leading to controlled area.
	84	W1	Wall site near doorway - room entrance.
	85	W2	Wall site near sink in wash area.
	86	W3	Wall site near door leading to controlled area.
	87	E1	Rodac sample on bench designating class transition area.
Surface Swab			
	Test ID	Test ID User Ref	Test Site Description
	88	S1	Swab sample within sink.
Production Room 102 Bottle Storage		Prod102	
Non Viable Particulate			
	Test ID	Test ID User Ref	Test Site Description
	79	P1	Particulate count in center of room.
RCS Air Sample			
	Test ID	Test ID User Ref	Test Site Description
	78	R1	RCS airborne contamination sample in center of room.
Rodac TSA Plate			
	Test ID	Test ID User Ref	Test Site Description
	73	F1	Floor site in doorway - room entrance.
	74	F2	Floor site in center of room.
	75	F3	Floor site in corner of room.
	76	W2	Wall site near doorway - room entrance.
	77	W2	Wall site on near wall above stored bottles.
Production Room 103 Bottling		Prod103	
Non Viable Particulate			
	Test ID	Test ID User Ref	Test Site Description
	71	P1	Particulate count within laminar flow curtains.
	72	P2	Particulate count in center of room.
RCS Air Sample			
	Test ID	Test ID User Ref	Test Site Description
	68	R1	RCS airborne contamination sample within laminar flow curtains.
	69	R2	RCS airborne contamination sample in center of room.
	70	R3	RCS airborne contamination sample in room corner near air return grate

**Environmental Monitoring
System**

Report Date: 10/20/99

Group Assignments

Facility: **EMS Test Facility**

Weekly Tests	Group ID	2
Production Room 103 Bottling		Prod103
Rodac TSA Plate		
Test ID	Test ID User Ref	Test Site Description
59	F1	Floor site in doorway - room entrance.
60	F2	Floor site within laminar flow curtains near bottling equipment.
61	F3	Floor site in center of room.
62	F4	Floor site near work surface.
63	E1	Rodac sample on bottling equipment within laminar flow curtains.
64	E3	Rodac sample on door handle.
65	W1	Wall site on far wall near air return grate.
66	W2	Wall site near laminar flow curtains.
67	W3	Wall site above countertop.
Production Room 104 Capping		Prod104
Non Viable Particulate		
Test ID	Test ID User Ref	Test Site Description
57	P1	Particulate count within laminar flow curtains.
58	P2	Particulate count in center of room.
Rodac TSA Plate		
Test ID	Test ID User Ref	Test Site Description
47	F1	Floor site within laminar flow curtains near capper.
48	F2	Floor site in doorway - room entrance.
49	F3	Floor site between workstations near countertop.
50	F4	Floor site in room corner - general cleanliness assessment.
51	E1	Rodac site on capping equipment within laminar flow curtains.
52	E2	Rodac site on capping equipment within laminar flow curtains.
53	E3	Rodac site on production surface.
54	W1	Wall site on window near laminar flow curtains.
STA Plate		
Test ID	Test ID User Ref	Test Site Description
55	S1	STA airborne contamination sample near capping equipment.
56	S2	STA airborne contamination sample in center of room.
Production Room 205 Raw Material Storage		Prod205
Non Viable Particulate		
Test ID	Test ID User Ref	Test Site Description
121	P1	Particulate count in center of room.
RCS Air Sample		
Test ID	Test ID User Ref	Test Site Description
120	R1	RCS airborne contamination sample in center of room.

Environmental Monitoring System

Report Date: 10/20/99

Group Assignments

Facility: EMS Test Facility

Weekly Tests	Group ID	2
Production Room 205 Raw Material Storage		Prod205
Rodac TSA Plate		
Test ID	Test ID User Ref	Test Site Description
115	F1	Floor site near doorway - room entrance.
116	F2	Floor site in center of room.
117	F3	Floor site near desk in corner of room.
118	W1	Wall site near doorway - room entrance.
119	W2	Wall site near stored raw materials.
Production Room 206 Personnel Prep Area		Prod206
Non Viable Particulate		
Test ID	Test ID User Ref	Test Site Description
114	P1	Particulate count in center of room.
RCS Air Sample		
Test ID	Test ID User Ref	Test Site Description
113	R1	RCS airborne contamination sample in center of room.
Rodac TSA Plate		
Test ID	Test ID User Ref	Test Site Description
103	F1	Floor site near doorway - room entrance.
104	F2	Floor site near sinks 1 and 2.
105	F3	Floor site near sinks 2 and 3.
106	F4	Floor site near lockers and bench.
107	W1	Wall site near doorway - room entrance.
108	W2	Wall site near sink 3.
109	W3	Wall site near lockers.
Surface Swab		
Test ID	Test ID User Ref	Test Site Description
110	S1	Swab sample within sink 1.
111	S2	Swab sample within sink 2.
112	S3	Swab sample within sink 3.
Production Room 207 Tablet Milling		Prod207
Non Viable Particulate		
Test ID	Test ID User Ref	Test Site Description
140	P1	Particulate count within laminar flow curtains.
141	P2	Particulate count in center of room.
Rodac TSA Plate		
Test ID	Test ID User Ref	Test Site Description
132	F1	Floor site within laminar flow curtains near tablet miller.
133	F2	Floor site near doorway - room entrance.
134	F3	Floor site near work surface.
135	F4	Floor site in center of room.
136	W1	Wall site near doorway - room entrance.

Environmental Monitoring System

Report Date: 10/20/99

Group Assignments

Facility: EMS Test Facility

Weekly Tests

Group ID 2

Production Room 207 Tablet Milling

Prod207

STA Plate

	Test ID	Test ID User Ref	Test Site Description
	138	S1	STA airborne contamination sample within laminar flow curtains.
	139	S2	STA airborne contamination sample in center of room.

Surface Swab

	Test ID	Test ID User Ref	Test Site Description
	137	S1	Swab sample on tablet milling equipment.

Production Room 208 Packaging

Prod208

Non Viable Particulate

	Test ID	Test ID User Ref	Test Site Description
	131	P1	Particulate count in center of room.

Rodac TSA Plate

	Test ID	Test ID User Ref	Test Site Description
	122	F1	Floor site near boxing equipment.
	123	F2	Floor site near doorway - room entrance.
	124	F3	Floor site in center of room.
	125	F4	Floor site near sink.
	126	W1	Wall site near doorway - room entrance.
	127	W2	Wall site near boxing equipment.
	128	E1	Rodac site on boxing equipment.

STA Plate

	Test ID	Test ID User Ref	Test Site Description
	130	S1	STA airborne contamination sample in center of room.

Surface Swab

	Test ID	Test ID User Ref	Test Site Description
	129	S1	Swab sample within sink.

Production Room 209 Lyophilization

Prod209

Non Viable Particulate

	Test ID	Test ID User Ref	Test Site Description
	153	P1	Particulate count within laminar flow curtains.
	154	P2	Particulate count in center of room.

Rodac TSA Plate

	Test ID	Test ID User Ref	Test Site Description
	142	F1	Floor site within laminar flow curtains between lyophilizers 1 and 2.
	143	F2	Floor site within laminar flow curtains between lyophilizers 2 and 3.
	144	F3	Floor site in center of room.
	145	F4	Floor site near work surface.
	146	W1	Wall site near doorway - room entrance.

**Environmental Monitoring
System**

Report Date: 10/20/99

Group Assignments

Facility: **EMS Test Facility**

Weekly Tests	Group ID	2	
Production Room 209 Lyophilization		Prod209	
Rodac TSA Plate			
	Test ID	Test ID User Ref	Test Site Description
	147	W2	Wall site above work surface.
	148	E1	Equipment site on the door of lyophilizer 1.
	149	E2	Equipment site on the door of lyophilizer 2.
	150	E3	Equipment site on the door of lyophilizer 3.
STA Plate			
	Test ID	Test ID User Ref	Test Site Description
	151	S1	STA airborne contamination sample within laminar flow curtains.
	152	S2	STA airborne contamination sample in center of room.

Environmental Monitoring System

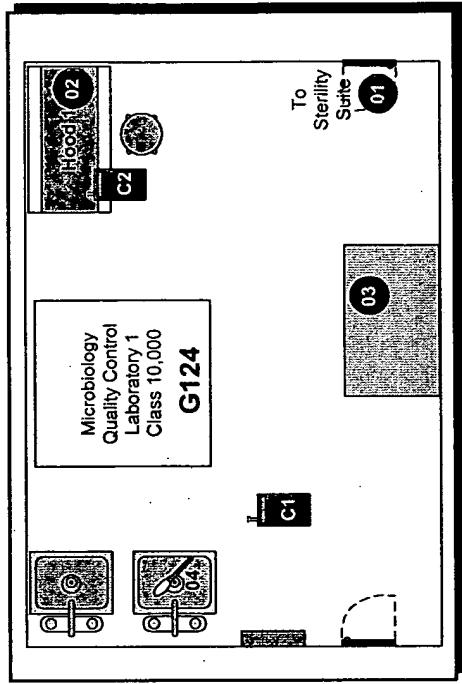
Report Date: 10/20/1999

EMS Test Facility

Room ID **4** Room Ref No **A174**
Room Description **Micro Lab 1**

Room Classification
Class 10.000

Production Area Classification
Not Classified



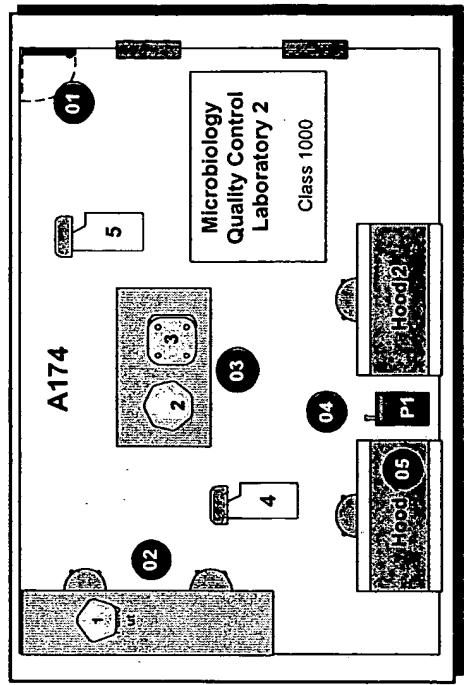
Test ID Ref	Test ID	Test Type	Classification	Site Desc	One Side	Alert Limits Min	Action Limits Max
	1	Fallout Plate	Not Classified	Counter	Yes	30	40
	1	STA Plate	Not Classified	Floor			
F1		Fallout Plate	Not Classified	Counter			
F2		Rodac TSA Plate	Not Classified	Floor			
F3		Rodac TSA Plate	Not Classified	Floor			
F4		Rodac TSA Plate	Not Classified	Floor			
F5		Rodac TSA Plate	Not Classified	Floor			
P1		Non Viable Particulate					
		Surface Swab					
		Surface Swab					
S2	ZZ1	RCS Air Sample					
		Swab sample within sink 1.					
		Swab sample within sink 2.					
		Touch plate taken on work surface.					

Environmental Monitoring System

Report Date: 10/20/1999

Survey Test Site Listing By Room

Facility	EMS Test Facility	
Room ID	Room Ref No	MicroLab2 A174
Room Description	Micro Lab2 A174	
Production Area Classification	Class 10.000	Class 100



Test ID Ref	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Action Limits Min	Action Limits Max
01	6	Floor in doorway / room entrance	Rodac TSA Plate	Not Classified	Floor	Yes	13	15
02	3	Floor between workstations approx 2 feet in front of work table.	Rodac TSA Plate	Class 10,000	Floor	Yes	4	6
03	5	Floor in center of room.	Rodac TSA Plate	Class 100	Floor	No	0	13
04	4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.	Rodac TSA Plate	Class 10,000	Floor	Yes	10	15
05	8	Site on work surface of laminar hood 1.	Rodac TSA Plate	Class 100	Critical Surface	Yes	12	15
E2	9	Site on work surface of laminar hood 2.	Rodac TSA Plate	Not Classified	Critical Surface	No	0	15
F5	7	Floor in room corner - assess general room cleanliness.	Rodac TSA Plate	Class 10	Floor	Yes	20	30
P1	12	Particulate count taken between laminar flow hoods.	Non Viable Particulate STA Plate	Not Classified	Counter	Yes	3	7
S1	11	Airborne contamination STA plate in center of room.	Touch Plate	Class 100	Counter	Yes	20	30
T1	10	Personnel touch plate.	Touch Plate	Class 10	Glove	Yes	15	20

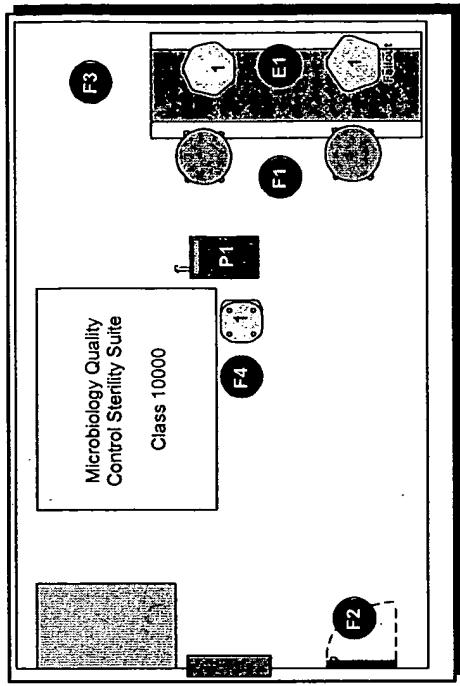
Environmental Monitoring System

Report Date: 10/20/1999

Facility	EMS Test Facility		
Room ID	6	Room Ref No	MicroSterility
Room Description	Micro Sterility Suite		
Production Area Classification	Class 100.000		
Class	100		

Room Classification
Class 100.000

Production Area Classification
Class 100



Test ID Ref	Test ID	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Action Limits Max	Action Limits Min
1	42		Touch plate taken within laminar flow hood.	Touch Plate	Not Classified	Glove	Yes	15	18
1	43		Fallout plate taken within laminar flow hood.	Fallout Plate	Not Classified	Critical Surface	Yes	10	15
1	44		STA airborne contamination sample taken in room center.	STA Plate	Not Classified	Counter	Yes	20	25
E1	41		Site on work surface of laminar flow hood.	Rodac TSA Plate	Not Classified	Critical Surface	Yes	15	18
F1	38		Floor site in front of laminar flow hood.	Rodac TSA Plate	Not Classified	Floor	Yes	20	25
F2	39		Floor site in doorway - room entrance.	Rodac TSA Plate	Not Classified	Floor	Yes	25	30
F3	40		Floor site in room corner - general cleanliness assessment.	Rodac TSA Plate	Not Classified	Floor	Yes	25	30
P1	45		Particulate count taken in room center.	Non Viable	Not Classified	Counter	Yes	2	5
WFI-000-1	1432		Point Of Use site at WFI Drop	Particulate	Not Classified	Water	No	6	7
				Water pH				6	8

Environmental Monitoring System

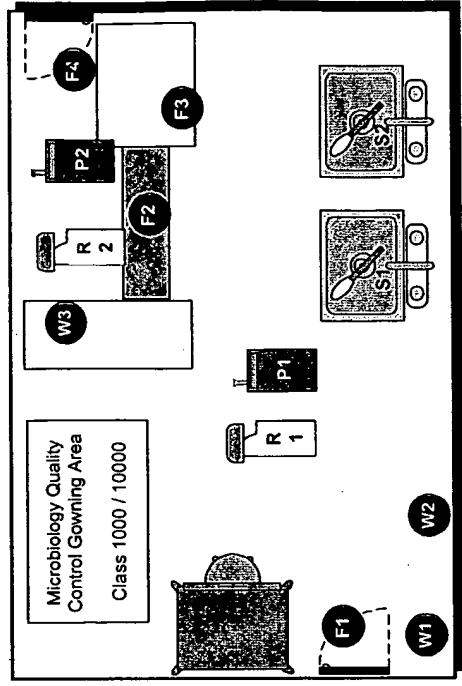
Report Date: 10/20/1999

EMS Test Facility

Room ID 7 Room Ref No MicroGowning
Room Description Micro Gowning Area

Room Classification
Class 10.000

Production Area Classification
Not Classified



Test ID Ref	Test ID	Test Description	Test Type	Classification	Site Desc	One Side	Action Limits Min	Action Limits Max
F1	25	Floor site in doorway - room entrance.	Rodac TSA Plate	Not Classified	Floor	Yes	20	40
F2	26	Floor site on wash side of bench designating class transition area.	Rodac TSA Plate	Not Classified	Floor	Yes	25	40
F3	27	Floor site on clean site of bench designating class transition area.	Rodac TSA Plate	Not Classified	Floor	Yes	15	25
F4	28	Floor site in doorway leading to controlled area.	Rodac TSA Plate	Not Classified	Floor	Yes	15	20
P1	36	Particulate count taken in center of wash area.	Non Viable Particulate	Not Classified	Counter	Yes	3	7
P2	37	Particulate count taken in center of clean area.	Non Viable Particulate	Not Classified	Counter	Yes	2	5
R1	34	RCS airborne contamination sample taken in center of wash area.	RCS Air Sample	Not Classified	Counter	Yes	40	50
R2	35	RCS airborne contamination sample taken in center of clean area.	RCS Air Sample	Not Classified	Counter	Yes	30	40
S1	32	Swab sample within sink 1.	Surface Swab	Not Classified	Work Surface	Yes	50	75
S2	33	Swab sample within sink 2.	Surface Swab	Not Classified	Work Surface	Yes	50	75
W1	29	Wall site near doorway - room entrance.	Rodac TSA Plate	Not Classified	Wall	Yes	30	45
W2	30	Wall site on near wall - general cleanliness assessment.	Rodac TSA Plate	Not Classified	Wall	Yes	50	65
W3	31	Wall site near door leading to controlled area.	Rodac TSA Plate	Not Classified	Wall	Yes	25	35

Environmental Monitoring System

Report Date: 10/20/1999

Group Desc. **Weekly Tests**

Survey Control No.

Survey Date:

Survey Shift:

Backup Survey Worksheet

Facility: EMS Test Facility

Product:

Lot #:

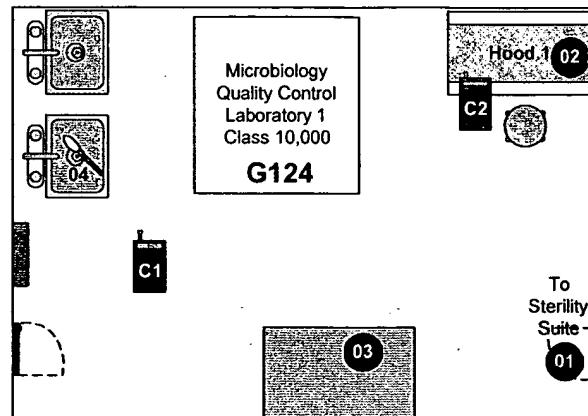
Room ID: 4 RefNo A174

Room Description

Micro Lab 1

Activity Level

- Normal
- Static.



Rodac/TSA Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Test By	Media Lot	Equipment ID	Sample ID
F1	13	Floor site in doorway - room entrance.					
F2	14	Floor site in front of laminar flow hood.					
F3	15	Floor site in doorway - to sterility suite.					
F4	16	Floor site in front of sinks.					
F5	17	Floor site in center of room.					
E1	18	Site on work surface of laminar flow hood.					

RCS Air Sample

Test ID Ref	Test ID	Test Site Description	Test Date	Test By	Media Lot	Equipment ID	Sample ID
ZZ1	22	Touch plate taken on work surface.					

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Test Date	Test By	Equipment ID	Sample ID
P1	24	Particulate count taken in room center.				

Fallout Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Test By	Media Lot	Equipment ID	Sample ID
1	21	Fallout plate within laminar flow hood.					

STP Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Test By	Media Lot	Equipment ID	Sample ID
1	23	Airborne contamination count taken in center of room.					

Reviewed By: _____

Date: _____

Page: 1 of 22

Environmental Monitoring System

Report Date: 10/20/1999

Group Desc. **Weekly Tests**

Survey Contol No.

Survey Date:

Survey Shift:

Backup Survey Worksheet

Facility: **EMS Test Facility**

Product:

Lot #:

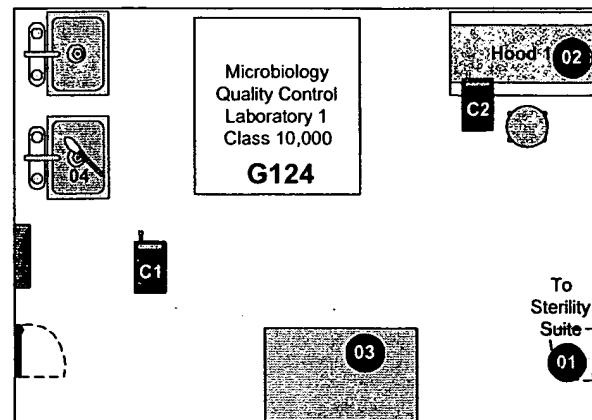
Room ID: 4 RefNo A174

Room Description

Micro Lab 1

Activity Level

- Normal
- Static



STA Plate			Test Date	Media Lot	Sample ID
Test ID Ref	Test ID	Test Site Description	TestBy	Equipment ID	
Surface Swab			Test Date	Media Lot	Sample ID
Test ID Ref	Test ID	Test Site Description	TestBy	Equipment ID	
S1	19	Swab sample within sink 1.			
S2	20	Swab sample within sink 2.			

Reviewed By: _____

Date: _____

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Environmental Monitoring System

Report Date: 10/20/1999

Group Desc. **Weekly Tests**

Survey Contol No. _____

Survey Date: _____

Survey Shift: _____

Backup Survey Worksheet

Facility: EMS Test Facility

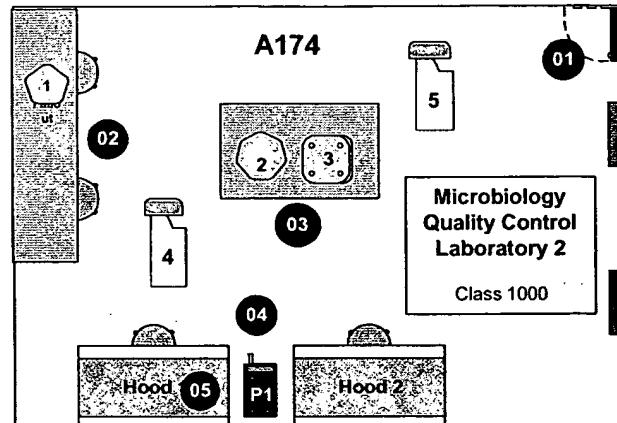
Product: _____

Lot #: _____

Room ID: 5 RefNo MicroLab2 A174

Room Description
Micro Lab2 A174

Activity Level
 Normal
 Static



Rodac TSA Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
02	3	Floor between workstations approx 2 feet in front of work table.	_____	_____	_____	_____
04	4	Floor Between hood #1 and hood #2. Sample approx 2 feet in front.	_____	_____	_____	_____
03	5	Floor in center of room.	_____	_____	_____	_____
01	6	Floor in doorway / room entrance	_____	_____	_____	_____
05	8	Site on work surface of laminar hood 1.	_____	_____	_____	_____
E2	9	Site on work surface of laminar hood 2.	_____	_____	_____	_____

Non Viable Particulate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
P1	12	Particulate count taken between laminar flow hoods.	_____	_____	_____	_____

Touch Plate

Emp/Tech ID	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
	10	Personnel touch plate.	_____	_____	_____	_____

STA Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
S1	11	Airborne contamination STA plate in center of room.	_____	_____	_____	_____

Reviewed By: _____

Date: _____

Page: 3 of 22

Environmental Monitoring System

Report Date: 10/20/1999

Group Desc. **Weekly Tests**

Survey Contol No. _____

Survey Date: _____

Survey Shift: _____

Backup Survey Worksheet

Facility: **EMS Test Facility**

Product: _____

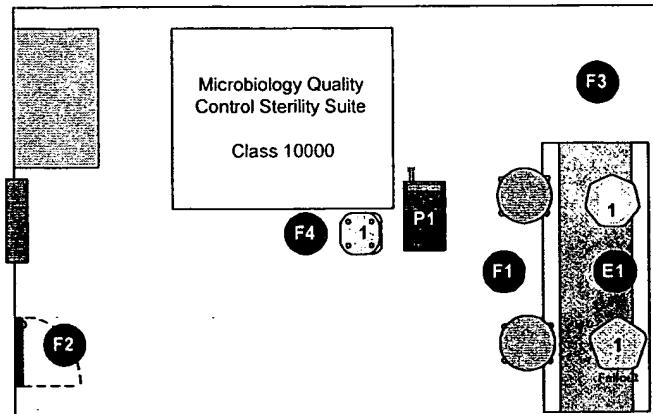
Lot #: _____

Room ID: 6 RefNo MicroSterility

Room Description
Micro Sterility Suite

Activity Level

- Normal
- Static



Rodac/TSA Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
F1	38	Floor site in front of laminar flow hood.	_____	_____	_____	_____
F2	39	Floor site in doorway - room entrance.	_____	_____	_____	_____
F3	40	Floor site in room corner - general cleanliness assessment.	_____	_____	_____	_____
E1	41	Site on work surface of laminar flow hood.	_____	_____	_____	_____

Non-Viable Particulate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Reading	Sample ID
Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Reading	Sample ID
P1	45	Particulate count taken in room center.	_____	_____	_____	_____	_____

Touch Plate

Emp/Tech ID	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
Emp/Tech ID	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
	42	Touch plate taken within laminar flow hood.	_____	_____	_____	_____

STA Plate

Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
Test ID Ref	Test ID	Test Site Description	Test Date	Media Lot	Equipment ID	Sample ID
1	44	STA airborne contamination sample taken in room center.	_____	_____	_____	_____

Reviewed By: _____

Date: _____

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Environmental Monitoring System

Organism Species Listing

Report Date Wednesday, January 16, 2002

Bacteria

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Bacteria	2	1	Bacillus stearothermophilis	N
	3	1	Bacillus circulans	N
	4	1	Bacillus cereus	N
	5	1	Bacillus coagulans	Y
	6	1	Clostridium acetobutyl	N
	7	1	Pseudomonas aeruginosa	N
	8	1	Pseudomonas fluorescens	N
	9	1	Staphylococcus aureus	N
	10	1	Salmonella arizona	N
	18	1	Bacillus subtilis	Y
	45	1	New Org ID	Y
	47	1	Test Organism	N
Total Bacteria		12		

Fungi

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Fungi	13	4	Fungi NOD	N
Total Fungi		1		

Mold

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Mold	12	3	Mold NOD	N
Total Mold		1		

Other

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Other	23	11	Other NOD	N
Total Other		1		

Yeast

Genus Desc	Genus/Species ID	Organism Type	Genus/Species Name	Objectionable
Yeast	11	2	Yeast NOD	N
Total Yeast		1		

